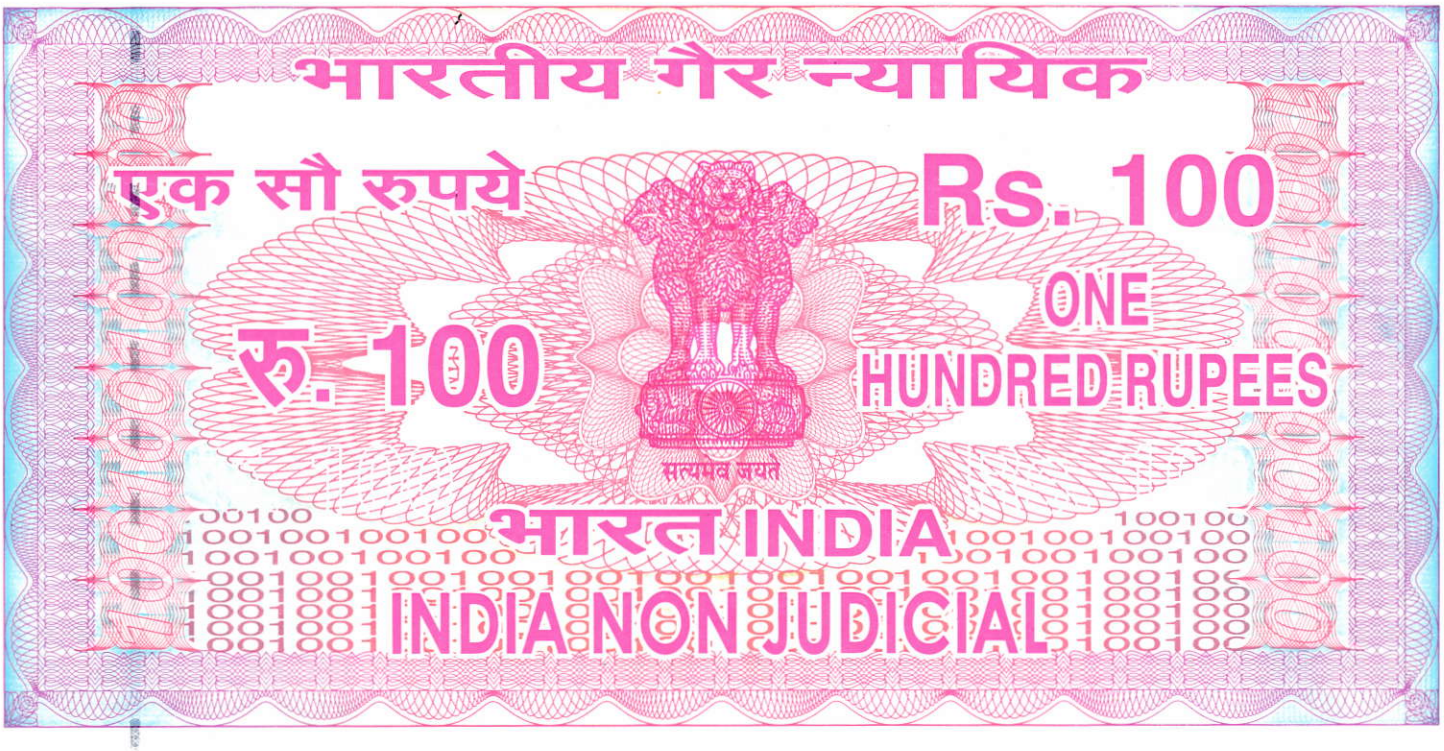

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AZ 532307

તારીખ : 28 SEP 2016 ૨૦૧૬

નામ :

LAMBDA THERAPEUTIC RESEARCH LTD.
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad-380 061.

ઠેકાણું :

કે. આર. પાટડીયા
લા. નં. એસ.બી. ૨૪૬, ૨૪૩/૧૯૮૬
અમદાવાદ નારણપુરાના સણંદી
લેનારની સહી.....

Clinical Trial Agreement

Lambda Therapeutic Research Ltd.

Plot No. 38, Survey no. 388, Near Silver Oak Club,
S G Highway, Gota,
Ahmedabad 380061,
Gujarat, India.

(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
2nd Floor, Chinubhai Centre,

Dr. Ashish Deshmukh, Dermatologist

LAMBDA
Research Accelerated

Ashram Road,
Ahmedabad- 380009,
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND:

Dr Ashish Deshmukh
Professor and Head, Skin & VD Department
Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003. MS. India.

(Hereinafter referred to as the "Investigator")

AND:

Mahatma Gandhi Mission's Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003. Maharashtra. India.

(Hereinafter referred to as the "Institute")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN:

Lambda Therapeutic Research Ltd.

Plot No. 38, Survey no. 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 380061, Gujarat, India.

(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
2nd Floor, Chinubhai Centre,
Ashram Road,
Ahmedabad- 380009,
Gujarat. India.
(Hereinafter referred to as the "Sponsor")

AND:

Dr Ashish Deshmukh
Professor and Head, Skin & VD Department
Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003. MS. India.

(Hereinafter referred to as the "Investigator")

AND:

Mahatma Gandhi Mission's Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003. Maharashtra. India.

(Hereinafter referred to as the "Institute")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.

Intas Pharmaceuticals Limited. has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A Randomized, Double-Blind, Placebo-Controlled, Three arm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two Tacrolimus 0.1% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis"** ("Clinical Trial") to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	**Tacrolimus 0.1% Ointment** (Test) Protopic® (tacrolimus) [Reference] **Manufactured by:** Intas Pharmaceuticals Limited **Manufactured for:** Intas Pharmaceuticals Limited
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization
"Declaration of Helsinki"	The 1996 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.

"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients

and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);

b) Progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) Ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) To allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure.

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol.

i) Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study.

j) Retention of Investigational Medicinal Products at site after completion of study as per regulatory requirements.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **7 to 9 patient** within **1** months; minimum expected recruitment rate from the site is **07 patients per month** on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of **6**

months; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within **3** working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 Payment terms

LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. Lambda will have oversight on patient reimbursement records maintain at the site.

6 Period of validity of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

- Archival of study documents including source data as referred to in para 2.7 and 14.3
- Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
- Confidentiality as per para 11

7 Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor.

8 Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9 Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10 Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

11 Confidentiality

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and

extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) Is already in the public domain at the time of disclosure

b) Becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) Was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12 Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such

purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13 Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14 Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.

2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.

3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.

4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.

5. The total number of patients required to be randomised is reached before the end of the recruitment period.

6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.

7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.

15 Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period,

the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO

Address:	Lambda Therapeutic Research Ltd Plot No. 38, Survey no: 388, Near Silver Oak Club, S G Highway, Gota Ahmedabad 380061, Gujarat, India.
Telephone:	+91 79 4020 2020
Fax:	+91 79 4020 2021
Contact person:	**Dr. Kiran Marthak**

Investigator : **Dr. Ashish Deshmukh**

Telephone: 0240-6601100
Fax: 0240-2487727

Institution

Address: **Mahatma Gandhi Mission's Medical College & Hospital**
N-6 CIDCO, Aurangabad-431003. Maharashtra. India
Telephone: 0240-6601100
Fax: 0240-2487727
Contact person: Dr Rajesh Kadam

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ **Date:** 30/Sep/16

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd

Witness:

Sign: _____ **Date:** 30 Sep 2016.

Witness Name : **Mr. Dharmesh Domadia**

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Institute:

Sign: _____ **Date:** 15/10/2016

Name: **Dr A G Shroff**
Designation: **Dean**

Address: **Mahatma Gandhi Mission's Medical College & Hospital**
N-6 CIDCO, Aurangabad-431003. Maharashtra. India

Witness:

Sign: _____ **Date:** 15/10/16.

Witness Name: **Dr Pravin Suryawanshi**

Designation: **Deputy Dean**

Department: **Surgery Department**

Institute Name: **Mahatma Gandhi Mission's Medical College & Hospital**
N-6 CIDCO, Aurangabad-431003. Maharashtra. India

Investigator: Dr. Ashish Deshmukh

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator:

Sign: _____ **Date:** 5/10/2016

Name: **Dr. Ashish Deshmukh**
Designation: **Principal Investigator**
Address: **Professor and Head, Skin & VD department**
Mahatma Gandhi Mission's Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003. MS. India.

Witness:

Sign: _____ **Date:** 15/10/2016

Witness Name : Dr Rajesh Kadam

Witness Address: **Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003. MS. India**

Schedule A

Study Protocol

Protocol No: 175-14

"A Randomized, Double-Blind, Placebo-Controlled, Three arm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two Tacrolimus 0.1% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis"

Schedule B
Budget and Payment Agreement:

(I) Budget

INVESTIGATOR GRANT BREAKUP							
Items	**Visit 01**	**Visit 02**	**Visit 03**	**Visit 04**	**Visit 05**	**Visit 06**	**Total**
Investigator Grant	5000	2500	3000	2500	2500	1500	17000
Co-ordinator Grant	1500	500	1000	1000	1000	500	5500
ECG (12 Lead)	500				500		1000
Administrative Charges	200	200	200	200	200	200	1200
Institute Overhead (30 %)	1950	900	1200	1050	1050	600	6750
PK Sample Charges			500				500
Patient Compensation	500	500	1000	500	500		**3000**
Total Grant	9650	4600	6900	5250	5750	2800	34950
Unscheduled Visit : 1500/UV							

* Screen failure payment will be paid for 20% patient of total screened patients

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges
g. Archival Charges

(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum for every complete and evaluable patient as defined in the payment schedule.

b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately

c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

e) Central Laboratory costs will be paid by Lambda on behalf of Sponsor.

f) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

g) **Patient conveyance/compensation** will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **Service tax applicable as per union budget rules.**

h) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

i) Payment mentioned under "Final Payment" will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & Details of Payee are:

Payee	: MGM Medical College, Aurangabad
Payee Address	: N-6 CIDCO, Aurangabad
PAN / TAN Number	: AAATM4256E

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

   The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:
   - all study related activities such as conduct of visits and eCRF completion
   - time and effort of investigators and other site staff
   - study coordinator salary
   - electricity expenses for use of equipment for study conduct
   - procurement of any study related material
   - all diagnostic tests and other investigations (like Hb level measurement etc)
   - housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
   - Phlebotomy expenses for safety samples
   - usage of internet while filling of eCRF
   - Patient conveyance/compensation which will be on a pro rata basis
   - miscellaneous (telephone, fax, courier, etc)
   - All overhead costs.

   Not included are (which are separate and in addition to per patient payment):
   - EC submission fee
2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .
9. All screen failure patients payments will be made post LPLV.

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

ગુજરાત गुजरात GUJARAT

AV 411431

નંબર: .... રૂ. ....

તારીખ: .... માહે .... સને ૨૦૧૬

નામ: 2 1 APR 2016

સરનામું:

શૈલેષકુમાર વાસુદેવભાઈ ત્રિવેદી

લેનાર ની સહી: ....

Karmic Lifesciences LLP
Unit No.-02, Ground Floor,
Reliable Plaza, Plot No.-K10
Thane Belapur Road, Airoli,
Navi Mumbai-400708

CLINICAL TRIAL AGREEMENT

PROTOCOL No. KLS-PH-041604

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date fully executed by the parties (the **"Effective Date"**) and entered into by and between

KARMIC LIFESCIENCES LLP, a limited liability partnership, incorporated under the Limited Liability Partnership Act, 2008 having its registered office at Unit No. G-02, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai – 400 708 (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its Affiliates, partners, employees, assignees, agents and successors-in-interest) and

DR. DEEPAK SADASHIV BHOSLE, presently employed at is Department of Pharmacology, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India (hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns) and

Mahatma Gandhi Mission's MEDICAL COLLEGE & HOSPITAL , situated at N-6, CIDCO, Aurangabad – 431003, Maharashtra, India (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest) and

Whereas, ITC Limited, having its registered office at Virginia House, 37, J.L. Nehru Road, Kolkata – 700 071, ("the Sponsor") through its Agent CRO desires the Institution to conduct study titled as " A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus" and the Institution is willing to perform a clinical study of the test biscuits (study product) and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below);

For the purpose of this Agreement, "Affiliate" means, when associated with a Party to this Agreement, any entity which controls, is controlled by, or is under common control with, that Party. In this context, the term "Control" shall mean any one of the following: (1) Ownership by one entity, directly or indirectly, of at least fifty (50%) of the voting stock of another entity; or (2) Power of one entity to direct the management or policies of another entity, by contract or otherwise.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

The study of **evaluating the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus** shall be conducted, under the direction of the Principal Investigator, in treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as **Protocol ID No. KLS-PH-041604** and entitled **"A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus**", a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of the Sponsor by the CRO. Its representatives (alone or together with representatives from Sponsor) will be allowed access to all information resulting from this Study and Sponsor will have an unrestricted right to use such information.

CRO (alone or together with representatives from Sponsor) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor include but are not limited to the following: (i) to ensure Protocol adherence, (ii) to verify the data in the CRFs against source documents (Source Document Verification "SDV"), (iii) to check progress of the Study and to motivate, if necessary, (iv) to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records, (v) to check all data for possible SAEs and Adverse Events ("AE"(s)), (vi) to review signed informed consent forms for signatures and date of consent, (vii) to ensure accurate record of drug accountability, (viii) to ensure adequate storage of Study supplies, (ix) to collect completed CRFs, and (x) to discuss and help resolve any problems.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Individual Ethics Committee) or IRB (Institutional Review Board).

2. THE STUDY SCHEDULE

A. Study Initiation. All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

B. Enrollment. Principal Investigator will enroll minimum 90 Subjects (as per the randomization schedule provided) for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

C. **Study Documentation.** Case Report Forms (**"CRFs"**) must be satisfactorily completed within **5** (Five) days of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed within **Five (5) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be communicated to the Sponsor and CRO in writing within 24 hours of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries (**"DCFs"**) must be completed and returned to Sponsor and CRO within **three days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit.

3. PAYMENT

A. **BUDGET AND PAYMENT SCHEDULE**: CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the **"Budget and Payment Schedule"**). Payment shall be made by cheque payable to **MGM Medical College**. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any Subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a Subject's eligibility shall be addressed to and resolved by the Sponsor's Clinical and/or Medical Monitor identified in the Protocol prior to entry of any such Subject into the Study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.
The mailing address for checks shall be:

Address	MGM's Medical College, N-6,CIDCO, Aurangabad-431003, Maharashtra, India
Attention to	Dr. Deepak Bhosle

The further details for the payments should be provided as:

5	Account No.	0376104000000107
6	Branch Code/BSB	NA
7	NEFT/ RTGS code	NA

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** Sponsor will pay only Rs. 1000/- (Rupees One thousand only) per Subject for screen failure. The maximum ratio for screen failure Subjects shall be 2:1 i.e. maximum one screen failure per two randomized Subjects.

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. **IEC / IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC / IRB withdraw approval of the Study, at any time, the Principal Investigator shall be immediately notified by the Sponsor or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC / IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor. Principal Investigator will also be responsible for the direction of the Study in accordance with any applicable Institution policies. The Principal Investigator shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator or the Institution should inform CRO and Sponsor in the event of a discrepancy between the terms of the Protocol, this Agreement and its own Institution policies within twenty one (21) days of the Effective Date of this Agreement.

If Principal Investigator is an employee of Institution and will be signing this Investigator Agreement as an acknowledgement of understanding but not as a separate party, Principal Investigator will nonetheless be deemed to be a separate party to this Investigator Agreement with respect to the provisions in this Investigator Agreement related to confidentiality, intellectual property rights and publication rights and any provisions in this Investigator Agreement that designate Principal Investigator as the sole performing party.

Any change in the designated Principal Investigator will require CRO and/or Sponsor's express written consent. Notice of a proposed change in Principal Investigator will be given to CRO and Sponsor promptly. If Institution and CRO and/or Sponsor are unable to mutually agree to a replacement, CRO and/or Sponsor may terminate this Investigator Agreement immediately.

C. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor

Study (including without limitation all source documents and data, and correspondence involving the IEC / IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC / IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor **within forty eight (48) hours** of the telephonic notification. If a written response is required or oral inquiries are requested by the regulatory agency concerning any aspect of the Institution and/or Principal Investigator's activities pursuant to this Agreement, the Institution and Principal Investigator shall permit representatives of the Sponsor and/or CRO to review and comment on such response prior to its being sent to the regulatory agencies. In such event, Institution and/or Principal Investigator will permit representatives from CRO and/or Sponsor to be present at any such inspections, will provide CRO and/or Sponsor with copies or transcripts of such inquiries as well as copies of correspondence between Institution and/or Principal Investigator and the applicable regulatory authority and will notify CRO immediately in writing of any violation or deficiency noted by any such authority.

E. **Supplies.** The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the nutraceutical product to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the nutraceutical product is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the nutraceutical product and any of its derivatives. Within 30 (thirty) days following the completion or termination of the Study, all unused nutraceutical product, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the nutraceutical product, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the nutraceutical product hereunder, and/or the possession or use of the nutraceutical product by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the nutraceutical product or other transfer of title in or to the nutraceutical product. Further, the Principal Investigator shall use the nutraceutical product solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

F. **Study Records, Reports, and Data.**

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records during and after the term of this Agreement in compliance with the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice ("**Study Records**"). The Institution and Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **two (2) years** after the approval of the nutraceutical product for marketing or the formal discontinuation of the clinical development of the nutraceutical product or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Institution will give the Sponsor or CRO not less than sixty (60) days prior express written notice thereof, and if the Sponsor requests in writing, the Institution shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

ii. *Case Report Forms*. The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. They will then be forwarded to CRO for data management and to Sponsor as applicable. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to CRO and Sponsor. If CRFs are not complete, the Principal Investigator shall be obliged to complete them on request of CRO or Sponsor.

iii *Principal Investigator Study File and Archiving*

The Investigator shall prepare and maintain complete and accurate Study documentation in compliance with ICH-GCP standards and all Applicable Laws. Therefore, an Investigator Study file shall be prepared which contains all relevant documents necessary for the conduct of the Study including but not limited to the following: (i) signed Protocol and amendments, (ii) Investigator's Brochure and updates, (iii) EC composition, approval(s)/opinion correspondence/reporting, , (iv) CVs and signature sheet for key Study personnel (e.g. investigators, Study nurses), (v) signed Study agreements including financial agreement, (vi) Trial initiation report, (vii) approved and signed informed consent forms, (viii) Study subject insurance certificate, (ix) CRFs (investigator's copy), (x) data correction forms (copies), (xi) SAE documentation and related correspondence/reporting (xii) shipping/accountability/destruction records for investigational product and material, (xiii) Certificate of analysis, (xiv) instructions for handling of investigational product and material, (xv) central laboratory accreditation/certification and up-to-date reference ranges of normal values, (xvi) screening, enrollment, and monitoring logs and Study subject identification code list, and (xvii) Study-related correspondence with Sponsor or CRO.

iv *Annual Reports*

The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC / IRB.

v *Final Reports*

Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome ("**Final Report**") to the IEC / IRB. In addition, any Serious Adverse Events will be reported to the IEC / IRB.

G. **Reporting of Serious Adverse Event.** The Institution and Principal Investigator shall notify Sponsor of any Serious Adverse Events (SAEs) encountered in the Study within twenty four (24) hours of any SAEs in accordance with Applicable Laws, Regulations and guidelines and will cooperate with CRO and/or Sponsor in connection with any reports or filings related to such SAEs.

H. **Regulatory Compliance.**

i. Institution and Principal Investigator will comply with all applicable laws and regulations in its performance of activities under this Agreement. Institution and/or Principal Investigator will provide reasonable assistance to Sponsor so that Sponsor may comply with any applicable law or regulation in the performance of the activities under this Agreement.

ii. The Parties agree that Institution and Principal Investigator's use and disclosure of Study subject health and medical information is subject to compliance with applicable laws and regulations. The Parties, therefore, agree to take all reasonable steps to protect the confidentiality of any Study subject health and medical information that it has access to and comply with applicable laws. The obligations set forth in this Section shall survive the termination or expiration of this Agreement.

iii. If applicable, Institution and Principal Investigator will obtain a written informed consent form from each Study subject and will maintain a signed original of the written informed consent in the Study subject's records. Institution or Principal Investigator will provide CRO and/or Sponsor an opportunity to review and approve the content of the informed

iv. Institution and Principal Investigator will provide financial disclosures that may be reasonably requested by Sponsor so that Sponsor may fulfill its financial disclosure obligations under applicable laws, rules and regulations.

I. **Resignation of Principal Investigator.** The Institution shall inform CRO in case the Principal Investigator ceases to be associated with the Institution for any reason during the course of the Study. They shall also replace the Principal Investigator in case CRO so desires and render all assistance to safeguard patient safety and Study data.

5. CONFIDENTIALITY

A. **Confidential Information:** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the nutraceutical product and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the nutraceutical product or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the study product or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

E. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

6. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required. Sponsor reserves the right to delay any publication for a period not to exceed sixty (60) days of receipt of draft in order to obtain patent protection.

7. OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the nutraceutical product and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.**

i. All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived therefrom shall be the exclusive property of that Party.

ii. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

iii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the nutraceutical product or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.

iv. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

8. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. **Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify"**). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

B. ***Of the Sponsor.*** *The Sponsor represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the Sponsor's obligations under this Agreement, and (iii) this Agreement has been duly executed and*

C. No Other Representations or Warranties. Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

9. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Mumbai, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Mumbai, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Mumbai, India.

10. INDEMNIFICATION

A. Sponsor Indemnification. **The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents** (the "Institution Indemnitees") **from and against any amount paid or payable by Institution Indemnitee for any loss, damage and/or expense which would not have been suffered but for participation in the Study, but excluding treatment for any pre-existing condition due to any claim, demand, cost or judgment ("Claims") which may be made or instituted against them by a third party by reason of personal injury (including death) to any Study subject, which arises out of or is otherwise sustained as a direct result of (a) administration of nutraceutical product pursuant to the Protocol designated in the Study, (b) the performance of Study in accordance with the Protocol, (c) the failure of any covenant or representation made by the Sponsor in or in connection with the Agreement, the Protocol or the Study, (d) the negligence, error, omission or malfeasance of the Sponsor, or (e) any other material breach of this Agreement by the Sponsor; provided however, that Sponsor's indemnification obligations hereunder shall not apply to the extent that any Claim is attributable to:**

(i) the failure of any Institution Indemnitee to perform the Study in accordance with or otherwise to adhere to the terms of the Protocol or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of the Study; or

(ii) a failure of any Institution Indemnitee to comply with all applicable federal, state, or local laws, rules, regulations, requirements and policies of regulatory authority, or

(ii) any negligence, error, omission or malfeasance of any Institution Indemnitee; or

(iv) any material breach of this Investigator Agreement by any Institution Indemnitee,

(v) in the event that Institution Indemnitee fails to cooperate with and give such assistance to Sponsor as may reasonably be required for the efficient and prompt handling of any Claim or makes any admission or offer to settle in relation to any Claim;

provided, however, that Sponsor's indemnification obligations hereunder shall not apply to the extent that a Claim relates to any matter for which Institution or Principal Investigator is required to indemnify Sponsor as provided for in Section 10 B below.

B. Institution Indemnification. The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("Sponsor Indemnitees") from and against any amount paid or payable by any Sponsor Indemnitee for any Claims which may be made or instituted against any Sponsor Indemnitee by a third party by reason of personal injury (including death) to any Study subject, to the extent that such Claim is attributable to:

(i) the failure of any Institution Indemnitee to perform in accordance with or otherwise to adhere to the terms of the Protocol or any written instructions (including, without

(ii) a failure of any Institution Indemnitee to comply with all applicable federal, state, or local laws, rules, regulations, requirements and policies of regulatory authority, or

(iii) any negligence, error, omission or malfeasance of any Institution Indemnitee, or

(iv) the failure of any covenant or representation made by any Institution Indemnitee in or in connection with the Investigator Agreement, the Protocol or the Study, or

(v) any material breach of this Investigator Agreement by any Institution Indemnitee,

(vi) in the event that Sponsor Indemnitee fails to cooperate with and give such assistance to Institution as may reasonably be required for the efficient and prompt handling of any Claim or makes any admission or offer to settle in relation to any Claim;

provided, however, that the Institution's indemnification obligations hereunder shall not apply to the extent that a Claim relates to any matter for which Sponsor is required to indemnify an Institution Indemnitee as provided for in Section 10 A above.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage Claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnitee.

F. **Subject Injury.** The Sponsor shall reimburse the Principal Investigator or the Institution for reasonable and necessary medical expenses that are directly and reasonably incurred by Subjects in the treatment of adverse events caused by the nutraceutical product following their administration or use in accordance with the Protocol and that are not covered by the Subject's insurance or governmental programs providing such coverage, provided that such expenses are not attributable to the negligence or misconduct of the Institution Indemnitee or any other Institution personnel involved in the Study; and provided further that such expenses are not attributable to a failure of the Institution Indemnitee to conduct the Study in accordance with (i) this Agreement; (ii) the Protocol; (iii) all written instructions delivered by the Sponsor concerning administration of the Nutraceutical product; (iv) all applicable government laws, rules, regulations, requirements, and policies; (v) Study subject's primary disease or any concurrent disease not directly and solely caused by administration of the nutraceutical product in accordance with the Protocol or (vi) the Study subject's failure to comply with instructions contained in the informed consent executed by such Study subject or communicated to the Study subject by Study personnel or (vi) the manner required of a reasonable and prudent clinical investigator or physician. Institution and Principal Investigator shall ensure that the amounts charged to the Sponsor in connection with such reimbursed treatments do not exceed the reasonable and customary amount allowed by Institution to any third party for such treatments. All such payments by the Sponsor shall be secondary to the insurance of the Subject and contingent on the Subject reasonably cooperating with the Sponsor's investigation of the injury and its causes. No other compensation of any type will be provided by the Sponsor to the Subjects for injuries related to the Study. Institution agrees that it will not seek or collect, and will not assist the Study subject in seeking or collecting, reimbursement from any health insurance plan, PPO, or governmental medical plan or other government provided health coverage available to the Study subject for any medical expenses paid by Sponsor pursuant to this Agreement.

11. INSURANCE

A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of One (1) year thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations. Sponsor will provide evidence of its insurance upon request and will provide to the Institution, thirty (30) days prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

B. **Institution Insurance.**
Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions. Upon execution of this Agreement and every anniversary thereafter during the term of this Agreement, Institution shall provide the Sponsor with a certificate of insurance stating the limits of coverage. Institution shall provide to Sponsor and CRO thirty (30) days prior written notice of cancellation or material change of any insurance referred to herein.

This Clause 11 shall survive termination of this Agreement.

12. TERM AND TERMINATION

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(*v*), above, unless earlier terminated in accordance with this Agreement. This Agreement shall be deemed terminated when Institution and Principal Investigator have fulfilled their respective responsibilities as specified in this Agreement.

B. **Termination.**

i. Either Party may terminate this Agreement immediately upon written notice to the other if:

a. the authorization and approval to perform the Study in India is withdrawn by the applicable regulatory authority in India;

b. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable to continue to serve and a successor acceptable to both Institution and Sponsor is not available.

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, Sponsor will make payment to Institution for:

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects

vi. **Immediate Termination by the Sponsor.** The Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the nutraceutical product to the Institution.

vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all Study supplies, materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11,and 12 shall survive any termination of this Agreement for any reason.

13. MISCELLANEOUS

A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

Any notice to the Sponsor shall be addressed as follows:

Address : ITC Life Science and Technology Center, No.3. Phase I , Stage I,Peenya Industrial Area, Peenya, Bangalore - 560 058.

Attn: Dr. Yashwanth Pudakalakatti

Address: MGM's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India
Attn: Dr. Rajendra Bohra
Ph: +91-0240-6601100
e-mail: mgmmca@themgmgroup.com

Any notice to Principal Investigator shall be addressed as follows:

Address: MGM's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India
Attn: Dr. Deepak Bhosle
Ph: +91- 7770087870
e-mail: drdeepakbhosle@gmail.com

Any notice to CRO shall be addressed as follows:

Address: Kamic Lifesciences LLP, Unit No. 02, Ground Floor, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai- 400 708
Attention: Dr. Prashant Kirkire
Ph: +91-9930886030
E-mail: prashant.kirkire@karmiclifesciences.com

E. **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. **Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.

G. **Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

H. **Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. **Covenant Not to Hire**. Sponsor shall not, and shall not permit any of its Affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination

L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol and current applicable local regulatory requirements. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be emailed to the Medical Affairs Department of CRO for onward transmission to SPONSOR:

E-mail: safety@karmiclifesciences.com

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

Institution and CRO will be responsible to notify on time the health authorities in India.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

Institute

By:_____
(Signature)
Dr. Rajendra Bohra
Dean
Mahatma Gandhi Mission's Medical college and Hospital,
N-6 CIDCO, Aurangabad-431003. MH. India
04 NOV 2016
(Date)

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

Principal Investigator

By: _____
(Signature)

Dr. Deepak Bhosle
Principal Investigator
Mahatma Gandhi Mission's Medical college and Hospital,
N-6 CIDCO, Aurangabad-431003. MH. India

KARMIC LIFESCIENCES LLP

By: _____
(Signature)

Name : Dr. Prashant Kirkire
Designation : President

13 Dec 16
(Date)

EXHIBIT A: PROTOCOL

As annexure 1

Protocol No - Attached herewith

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : **Dr. Deepak Bhosle**

Site Address : Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant is as follows:

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
14504	Includes the following • PI and site team payment including Co- Investigator (s), Phlebotomist(s), Nurse(s), Dietician as applicable • Institutional overhead • Subject Travel Compensation (max to be paid INR 250/Visit/Subject
	Total Amount

Budget Bifurcation

Study Budget			INR	Comments
A	Investigator fee & Staff fees	Visit 1 (screening visit) –in case of screen failure	1000*	to be paid per subject @ 2:1 patient (for every 2 enrolled subject 1 screen fail) *inclusive of study staff fee for screen failures
		Visit 2 (enrollment visit)	2540	to be paid per enrolled subject
		Visit 5	1000	-
		Visit 7	3540	to be paid per completed subject
B	Study Staff Fee (inclusive of Coordinator & Phlebotomist Fee)	Visit 2 (enrollment visit) – Visit 7 (End of study visit)	1500	To be paid for per completing subject
C	Subject travel reimbursement	Visit 1 (screening visit) – Visit 7 (end of treatment)	1750	max to be paid per subject @ INR 250/visit
D	**ECG fees**	**Screening Visit**	300	to be paid per screened subject
D	**% Institutional overhead (30 %)**		2874	Will be paid as per the (A+B) per completed subject
	Total		14504	per completing subject

- **EC Charges/fees will be paid separately**
- **Central lab would be utilized for protocol specific blood analysis and payment would be done by CRO on behalf of sponsor**

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Schedule for the advance payment is as follows:

1 Study start up cost (Advance/ pre payment) INR. 10000/-

The advance payment (pre payment) provided to the PI will be adjusted against first three invoices raised by PI as per the PI grant.

The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.

Sponsor will pay only INR.1000/- amount for screen failure patients as per Exhibit A of this Agreement with the maximum ratio of 2:1 i.e. maximum one screen failure per two randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within thirty (30) days after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.
In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have forty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices

Send invoices to:
Contact Person: **Mr. Amit Pawar/Mr.Sagar Dhawale**
Address: Karmic lifesciences LLP, Unit No. G-02, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai – 400 708

Also send copy of Invoices through mail to contact person at **amit.pawar@karmiclifesciences.com** & **sagar.dhawale@karmiclifesciences.com**

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.

4. Each randomized subject after completion of the study visit can be given the reimbursements.
5. Please note that the total amount for three randomized patients i.e. INR. 43,512/- (fourty three thousand five hundred twelve only) will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
6. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.

- A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the site in the budget.

- In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made and entered into effective as of 23 Nov 2016, (hereinafter "Effective Date") by and between **BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED,** a company incorporated under the Companies Act, 1956 having its registered office at Indiabulls Finance Centre 6th Floor, Tower 1, Senapati Bapat Marg Elphinstone (W), Mumbai-400 013 **(hereinafter "SPONSOR")**

And

MGM Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431003, India **(hereinafter "INSTITUTION")**

And

PPD Pharmaceutical Development India Private Limited, 101-A Wing Fulcrum, Hiranandani Business Park, Sahar Road, Anderi East, Mumbai – 400 099 **(hereinafter "CRO")**

RECITALS

WHEREAS, SPONSOR conducts business in the research, development, manufacture and sale of pharmaceutical, nutritional and healthcare products, and

WHEREAS, SPONSOR desires INSTITUTION to conduct a clinical trial and INSTITUTION desires to conduct same, said trial being entitled:

Study Title: "A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total Hip Repalcement Surgery"

Protocol No. CV185158

(said study, as it may be amended or supplemented from time to time in accordance with this agreement, hereinafter referred to as the "Study"), and

WHEREAS, SPONSOR has contracted with CRO to coordinate and/or perform certain activities required for the conduct of the Study and to administer and disburse payments under Article 2 of this agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INSTITUTION and SPONSOR agree as follows:

Article 1 - The Study

1.1 The INSTITUTION shall, where required by applicable law, submit the Protocol for review and approval (i) in the case of all U.S. studies and any IND Study, to an appropriate Human Subject Institutional Review Board/Ethics Committee or equivalent body in accordance with Applicable Law (any such board, body or committee referred to hereinafter as the "IRB"), and (ii) in the case of a non-IND Study, to an appropriate independent review committee of scientists or other

qualified individuals as set forth under Applicable Law and in the Declaration of Helsinki (any such board, body or committee referred to hereinafter as the "IRB"). INSTITUTION shall conduct the Study in accordance with the Protocol approved by the INSTITUTION's IRB, as the same may be changed from time to time thereafter (hereinafter the "Protocol") and in accordance with prudent research practices and Applicable Law . Changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) by agreement of the INVESTIGATOR, INSTITUTION and SPONSOR. Changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by Applicable Law and/or the Protocol.

For the purposes of this Agreement, Applicable Law includes all applicable statutes, enactments, acts of legislature or Parliament, laws, ordinances, rules, by-laws, regulations, notifications, guidelines, policies, directions, directives and orders of any government authority, tribunal, board, court or recognised stock exchanges including but not limited to the US FDA rules and regulations, the International Conference of Harmonization Guidelines for Good Clinical Practices, India's Drugs and Cosmetics Act, 1940 and Good Clinical Practices ("Applicable Law").

1.2 **Dr. Girish Namdeorao Gadekar** (the "INVESTIGATOR") will serve as Investigator, will supervise the conduct of the Study, and may appoint such other individuals as INVESTIGATOR, in accordance with Applicable Law and/or the Protocol, may deem appropriate as subinvestigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "SUBINVESTIGATORS"). The INVESTIGATOR shall be responsible for leading and supervising any such team of SUBINVESTIGATORS. If **Dr.Girish Namdeorao Gadekar** should become unable to conduct the Study, INSTITUTION shall consult with SPONSOR regarding the appointment of a new investigator and if both parties cannot agree on a substitute, all further enrollment of subjects into the Study shall immediately cease. In the event that the Study ceases, the Investigator shall (a) forthwith inform the subjects of such, the IRB and all other regulatory authorities under Applicable Law, in writing regarding such termination of the Study; and (b) ensure all necessary therapy and follow up with the subjects as required by Applicable Law in the event INSTITUTION and SPONSOR are able to agree upon a substitute, both parties agree to work in good faith to amend this Agreement and any other documents to reflect such substitute to ensure compliance with all applicable laws, regulations and guidelines.

1.3 The INSTITUTION, SPONSOR, the INVESTIGATOR and each SUBINVESTIGATOR shall comply with the Protocol and with all Applicable Law and other governmental requirements in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

(a) INSTITUTION, the INVESTIGATOR and each SUBINVESTIGATOR shall, as the same may be required of each of them by Applicable Law and the Protocol, prepare, document and maintain records and case histories on case report forms supplied by SPONSOR or CRO (as instructed or authorized by SPONSOR), retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects (or their duly authorized representatives) participating in the Study.

(b) INSTITUTION, INVESTIGATOR and each SUBINVESTIGATOR shall implement and maintain all quality assurance quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with

the protocol and under Applicable Law.

(c) The INVESTIGATOR and each SUBINVESTIGATOR shall notify the SPONSOR, the IRB , the CRO and the relevant government bodies of all serious and unexpected adverse events in the course of the Study of which they become aware in accordance with Applicable Law and the Protocol.

(d) Upon reasonable notice and at reasonable times during the term of this Agreement, INSTITUTION, the INVESTIGATOR and each SUBINVESTIGATOR shall permit representatives of SPONSOR and CRO to examine their respective facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, the Protocol and Applicable Law; provided, that SPONSOR and CRO representatives may not review patient identifying information without proper written authorization from a Subject or except as required by law.

(e) The INVESTIGATOR will keep appropriate records of Study drug received, dispensed, used, and returned by subjects, as well as records of any Study drug returned to SPONSOR, in accordance with Applicable Law and the Protocol.

(f) INSTITUTION and INVESTIGATOR and SPONSOR acknowledge that it is possible that a regulatory or other governmental agency, acting within its scope of authority, may at some time take regulatory action against INSTITUTION because of actual or alleged deficiencies in studies not placed by SPONSOR or because of other alleged INSTITUTION defects. INVESTIGATOR and INSTITUTION agree to notify SPONSOR immediately by telephone or telefax of any such regulatory action taken or anticipated to be taken against INSTITUTION for any reason that may affect a Study governed by this Agreement and to provide a copy of any written correspondence received from a regulatory agency pertaining thereto.

INSTITUTION shall promptly notify SPONSOR of any request received by INSTITUTION from any applicable regulatory or other governmental agency to inspect or otherwise gain access to the information, data or materials pertaining to the Study performed by INSTITUTION under this Agreement. INSTITUTION shall promptly notify SPONSOR of such requests prior to permitting any third party access unless prior notice is not possible. INSTITUTION agrees to permit inspection of such information, data and materials by authorized representatives of such agencies as required by law. INSTITUTION will make reasonable efforts to segregate materials related to the Protocol, the Study and the Study Drug from any other materials that are the subject of such inquiry or inspection and will disclose only those documents and materials that are required to be disclosed during such inquiry or inspection. INSTITUTION will provide SPONSOR with copies of such notice(s) and related correspondence and permit SPONSOR representatives to attend such visits where such visits directly affect a Study governed by this Agreement. At SPONSOR's request and at a mutually agreeable time, INSTITUTION will accompany SPONSOR to such agencies to discuss relevant aspects of INSTITUTION's services performed hereunder.

1.4 SPONSOR shall provide, without cost, sufficient amounts of the Study drug to conduct the Study. INSTITUTION and INVESTIGATOR may not use or dispose of the Study drug in any way other than as specified in the Protocol.

1.5 CRO shall have such obligations and rights with respect to the Study performed under this Agreement as authorized by SPONSOR, which rights and obligations are set forth in a separate agreement between SPONSOR and CRO.

Article 2 - Compensation

2.1 In consideration of INSTITUTION's and INVESTIGATOR's participation in this Study and of their agreements hereunder, and to cover their respective costs connected with the conduct of the Study, the CRO shall pay to **"Ardent Clinical Research Services"** such amount to be determined and paid in the manner set forth in Exhibit A hereto. INSTITUTION will complete the Study within the maximum budget set forth on said Exhibit A, and will not commit to nor incur any expenses in excess of such maximum amount without SPONSOR's prior written consent. Each party agrees to discuss budgetary matters with the other party as either party may request from time to time. The parties acknowledge CRO shall, on behalf of SPONSOR, be responsible for administering and disbursing payments contemplated by this Article 2.1 in accordance with the schedule set forth in Exhibit A hereto.

2.2 The INSTITUTION and the INVESTIGATOR have elected to assign their right to receive payment under this Agreement to **"Ardent Clinical Research Services"** ("SMO") in accordance with Exhibit A. All payments made in respect of the INSTITUTION's and the INVESTIGATOR's performance under this Agreement shall be made to SMO. SMO will be responsible for compensating the INSTITUTION and all individuals and entities involved in the conduct of the Study, including the INVESTIGATOR. Neither SPONSOR nor CRO shall have any payment obligation directly to INSTITUTION, INVESTIGATOR or all such individuals and entities."

Article 3 - Institution Staff and Facilities

3.1 The Study shall be carried out at INSTITUTION under the review of its Institutional Review Board and under the supervision of the INVESTIGATOR. INSTITUTION will perform the Study in an efficient, ethical and professional manner and will use its best efforts to complete the Study within the time period estimated therefor.

3.2 INSTITUTION shall arrange and pay for all necessary laboratory and other facilities, equipment, supplies (other than the Study drug), and physicians and clinical support staff required to discharge its obligations under the Study.

3.3 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the INVESTIGATOR, any SUBINVESTIGATOR and any support staff used in the Study shall be solely a matter between INSTITUTION and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of INSTITUTION.

3.4 The INVESTIGATOR, each SUBINVESTIGATOR and any support staff shall comply with the terms of this Agreement to the same extent as INSTITUTION hereunder. INSTITUTION will take appropriate steps to inform each such person of his/her obligations hereunder and to obtain his/her agreement to abide by the terms and conditions of this Agreement.

3.5 The INVESTIGATOR hereby acknowledge and agree that payments due under this Agreement are pass-through payments from the SPONSOR. CRO will make said payments once funds are received by CRO from the SPONSOR. CRO shall exercise reasonable efforts to ensure timely receipt of pass-through payments from the SPONSOR.

Article 4 - Reports

4.1 INVESTIGATOR shall keep SPONSOR advised of the status of the Study via periodic reports provided to SPONSOR or CRO (as instructed by SPONSOR). The frequency of reports shall be mutually agreed to by SPONSOR and INVESTIGATOR, in accordance with requirements specified under any Applicable Law, and set forth in Exhibit A. If required by SPONSOR, there shall also be a final report of the Study presented to SPONSOR. INSTITUTION and INVESTIGATOR shall assist the SPONSOR in submitting any status reports as may be required under any Applicable Law to any regulatory authority specified under the Applicable Law.

4.2 All case report forms and other reports submitted to SPONSOR or CRO and all data generated hereunder shall become the property of SPONSOR and may be used by SPONSOR for any purpose without further obligation or liability to INSTITUTION. INSTITUTION shall have the right to obtain and use the data in order to publish the Study results as provided in Article 5 below, for continuing academic research purposes and for the treatment and medical care of any Study subject. A subject's individual medical records shall remain the property of the INSTITUTION. INSTITUTION will, where duly authorized or within the bounds of legal requirements, provide or make such medical records and individual subject data available to SPONSOR or CRO and such governmental agencies designated by SPONSOR. Study data shall be transmitted to SPONSOR or CRO by magnetic media or other mutually agreed upon method. Study medical records and data shall be retained by INSTITUTION for such period of time required by law and/or by the Protocol. INSTITUTION shall be entitled to retain, for archival purposes, a copy of the case report forms.

4.3 INSTITUTION agrees not to provide the Study data to any third party or to use the Study data in commercially-sponsored research without SPONSOR's prior written consent. INSTITUTION also agrees not to identify, either on a blinded or unblinded basis, subjects from this Study in order to benefit research conducted or sponsored by any third party, without SPONSOR's prior written consent. The foregoing shall not affect INSTITUTION's right to publish the Study results or to use the Study data for internal academic research as set forth in this Agreement, to disclose information required by law, or to disclose or use data for the medical care of any specific Study subject.

Article 5 - Publication

5.1 INSTITUTION and INVESTIGATOR may freely publish and disseminate the results of their investigative findings hereunder and shall solely determine the authorship and contents (including scientific conclusions and professional judgments) of any such paper. INSTITUTION or

INVESTIGATOR, as the case may be, shall provide SPONSOR with a copy of the papers prepared for publication by it, him/her or any SUBINVESTIGATORs at the earliest practicable time, but in any event not less than thirty (30) days prior to their submission to a scientific journal or presentation at scientific meetings and a reasonably detailed summary or abstract of any other oral or written publication not less than thirty (30) days prior to their submission or presentation. SPONSOR may comment upon, but may not make any editorial changes to, the results and conclusions set forth in the papers; however, if identified by SPONSOR, any SPONSOR Confidential Information (as defined below) that may be contained therein shall be deleted. SPONSOR personnel shall be acknowledged in accordance with customary scientific practice. SPONSOR may freely use, copy and disseminate any such manuscript following its publication without further obligation to INSTITUTION or INVESTIGATOR.

Article 6 - Confidential Information

6.1 In furtherance of the conduct of the Study, it may be necessary or desirable for the parties hereto to disclose proprietary, trade secret and/or other confidential information (hereinafter "Confidential Information") to one another or to the INVESTIGATOR. For purposes of this Agreement, Confidential Information of SPONSOR shall include information received from either SPONSOR or CRO. All such Confidential Information shall remain the property of the party disclosing same. Such Confidential Information disclosed by CRO shall be deemed as and remain the property of SPONSOR. The INVESTIGATOR and each party hereto agrees that any such Confidential Information disclosed to him or her, or to it or its employees, agents and contractors, shall be used only in connection with the legitimate purposes of this Agreement, shall be disclosed only to those who have a need to know it and are obligated to keep same in confidence, and shall be safeguarded with reasonable care; provided, however, that the disclosing party marks the Confidential Information as such at the time of disclosure (or, if disclosed verbally, such Confidential Information is reduced to writing and so marked within a reasonable period of time thereafter).

The foregoing confidentiality obligation shall not apply when, after and to the extent the Confidential Information disclosed

(i) is now, or hereafter becomes, generally available to the public through no fault of the receiving party or its employees, agents or contractors,

(ii) was already in the possession of the receiving party without restriction as to confidentiality at the time of disclosure as evidenced by competent written records, or

(iii) is subsequently received by the receiving party from a third party without restriction and without breaching any confidential obligation between the third party and the disclosing party hereunder.

Confidential Information may also be disclosed to the extent required by Applicable Law (including without limitation the filing and prosecution of patent applications), provided that the party making such disclosure of the other party's Confidential Information shall give maximum practical advance notice of same and request such confidential treatment of such disclosure from the recipient thereof as may be afforded by the Applicable Law. The terms of this Agreement shall not be disclosed to any third party, except as required by Applicable Law or with the permission of the other party; provided, however, that, without the consent of the other party, INSTITUTION may disclose the SPONSOR's and INVESTIGATOR's name, total grant amount, and a general, nonconfidential title of

the Study without SPONSOR's consent in INSTITUTION's customary publications therefor, and SPONSOR may disclose the terms of this Agreement in connection with any governmental filing relating to the drug approval process or any business opportunity.

6.2 In addition to the above, INSTITUTION and INVESTIGATOR specifically agree that they will not discuss the Study or the Study drug with any financial, securities, or industry analyst, or with the media, except as authorized in writing by SPONSOR. This obligation extends to (a) Confidential Information supplied by the SPONSOR or CRO, (b) data produced in the Study, and (c) any opinion of INSTITUTION or INVESTIGATOR that is informed, in whole or in part, directly or indirectly, by access to the Confidential Information or Study data.

Article 7 - Independent Contractor

7.1 The relationship of SPONSOR to INSTITUTION , SPONSOR to INVESTIGATOR and SPONSOR to CRO under this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed to place the parties in the relationship of employer and employee, partners, principal and agent, or joint venturers. Neither party shall have the power to bind or obligate the other party nor shall either party hold itself out as having such authority.

Article 8 - Term and Termination

8.1 This Agreement shall commence on the Effective Date of this Agreement and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study as provided in the Protocol.

8.2 This Agreement (or any Study conducted hereunder) may be terminated and/or further enrollment of subjects in a Study may be suspended:

(a) by SPONSOR, with or without cause, effective as of such date as SPONSOR may specify in such notice (which shall be not less than thirty (30) days prior notice for any termination of this Agreement without cause) to INSTITUTION, without penalty or liability therefor and payment of any further compensation hereunder except as may be provided in Exhibit A, provided, however, that SPONSOR shall have no obligation to pay for the Study if SPONSOR terminates this Agreement for material failure of INSTITUTION or INVESTIGATOR to follow the Protocol or breach of any material obligation under this Agreement;

(b) by INSTITUTION, either (i) if it believes such termination is necessary to protect the best interests of the Study subjects, or (ii) for a breach of a material provision hereof by SPONSOR, which breach is not cured by SPONSOR within thirty (30) days following receipt of written notice thereof from INSTITUTION;

(c) CRO may remove itself as a party to this Agreement upon thirty (30) days prior written notice to the other parties, if the agreement pursuant to which PPD Development LLC is providing services to Sponsor in connection with the Study is terminated or cancelled; or

(d) by written mutual agreement.

Upon such termination or suspension, the parties will meet and confer promptly to determine an appropriate phase-out for subjects already enrolled in the Study. Further, in the event of termination due to any reason, INVESTIGATOR shall assist SPONSOR in submitting any reports or meeting any requirements as may be required under Applicable Law.

8.3 Articles 1.3, 1.4, 2, 3, 4, 5.1, 6 and 9 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have based upon events occurring prior to the termination date.

Article 9 - General

9.1 Distinct from any medical expenses covered by Article 9.2 below, SPONSOR will indemnify and hold harmless INVESTIGATOR, any SUBINVESTIGATOR, INSTITUTION, its IRB, its affiliated corporations, and its and their directors, trustees, officers, employees and agents (collectively, the "Indemnitees") , from and against any amounts paid or payable by an Indemnitee to a Study subject resulting from claims, legal proceedings or causes of actions (collectively, "Claims") asserted or initiated by such subject based upon personal injury (including death) to such Study subject, which injury is sustained as a result of the administration of the Study drug in accordance with the Protocol, except to the extent such Claims, are attributable to:

(i) the failure of INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or any other INSTITUTION personnel involved in the performance of the Study to adhere to the terms of the Study protocol or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of the Study, or comply with Applicable Law, or

(ii) any negligent or wrongful act or omission, or willful malfeasance, of INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or any other INSTITUTION personnel (including employees, agents or independent contractors) involved in the performance of the Study.

It is a condition precedent to SPONSOR's indemnification obligations under this article 9.1 that each such Indemnitee seeking indemnity hereunder must (i) promptly notify SPONSOR of the assertion of any such Claims against it/him/her, (ii) authorize and permit SPONSOR to conduct and exercise sole control of the defense and disposition (including all decisions relative to litigation, appeal or settlement) of such Claims and (iii) fully cooperate with SPONSOR regarding any such Claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of SPONSOR's obligations hereunder. Subject to the foregoing, each Indemnitee may participate in any such Claims at its/his/her own cost and expense.

9.2 In the event of an injury occurring to the Study subject, such Study subject shall be provided free medical management in accordance with applicable laws as may be amended from time to time. In the event of a Study-related injury or death, the SPONSOR shall reimburse the costs of and to provide financial compensation in accordance with applicable laws as may be amended from time to time (except to the extent such costs are covered by the Study subject's

insurance or other third party coverage in accordance with applicable laws as may be amended from time to time). In the event of no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages in accordance with applicable laws as may be amended from time to time.

9.3 No right or license is granted under this Agreement by one party to the others either expressly or by implication, except those specifically set forth herein. Nothing contained within this Agreement shall impose an obligation of exclusivity on one party by the others. The parties reserve the right to enter into and participate in other activities (either alone or with another party) including, but not limited to, clinical trials and sponsored research projects.

9.4 All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of India, without regard or giving effect to its conflict of laws principles. Parties agree and irrevocably submit to the exclusive jurisdiction of the Mumbai courts to hear and determine any suit, action or proceeding and to settle any disputes which may arise out of or in connection with this Agreement. This Agreement, including the annexed Exhibit(s), sets forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof This Agreement may not be assigned by one party without the prior written consent of the other parties (not to be unreasonably withheld). This Agreement may not be changed or supplemented, except by a writing executed by INSTITUTION, SPONSOR and CRO. No failure or delay in exercising any right hereunder will be considered a waiver thereof unless expressly waived in writing by the party to be charged therewith. No waiver on one occasion will be considered a continuing or subsequent waiver. The person signing below on behalf of a corporation or other entity represents that he or she has the full power and authority to enter into this Agreement on behalf of such entity.

9.5 All legal notices to be given by one party to the others shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the parties at their respective addresses first set forth above to the attention of:

If to the INSTITUTION,
to:
MGM Medical College & Hospital ,
N-6 CIDCO, Aurangabad-431003,
MH India.
Telephone no:- 0240 660 1100
Attn:Dr.A .G Shorff

If to the SPONSOR,
to:
Indiabulls Finance Centre 6th Floor,
Tower 1, Senapati Bapat Marg
Elphinstone (W), Mumbai-400 013

If to the CRO,
to:
PPD Pharmaceutical Development India Pte Ltd
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Anderi East,Mumbai – 400 099
Attn.:Rashmi Chitgupi

or to such other address as either may designate from time to time to the other. Any notice shall be effective as of its date of receipt.

9.6 SPONSOR will not use the name of INSTITUTION, or a variant thereof, in any advertising or promotional material or make any representation relative to the Study drug which would constitute an express or implied endorsement by INSTITUTION of any commercial product or service (and will not authorize others to do so), except as may be required by law or with the INSTITUTION'S written permission. INSTITUTION will not use SPONSOR's name, or a variant thereof, for any advertising or promotional purpose without SPONSOR's prior written consent.

9.7 INSTITUTION shall promptly disclose to SPONSOR any discovery or invention ("Invention") made by INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or other Study personnel in the performance of the Study. All such Inventions shall be the exclusive property of the SPONSOR, and INSTITUTION and INVESTIGATOR shall assign, and shall take appropriate steps to ensure that all of its Study personnel are obligated to assign, to SPONSOR all rights, title and interests each may have in any such Invention and will cooperate to effect the foregoing.

9.8 INSTITUTION hereby certifies to SPONSOR that INSTITUTION has not used, and will not use the services of any person debarred under the Generic Drug Enforcement Act of 1992, as amended, in any capacity in connection with any of the services or work provided hereunder or for or on behalf of SPONSOR or any of its affiliates, subsidiaries or divisions and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. It is understood and agreed that this certification imposes a continuing obligation upon INSTITUTION to notify SPONSOR of any change in the truth of this certification.

9.9 So that SPONSOR may fulfill its certification and other financial disclosure obligations under 21 CFR Part 54 to the United States Food and Drug Administration and such other Applicable Laws and regulations as may from time to time be or become applicable with respect thereto, the INVESTIGATOR and each SUBINVESTIGATOR shall provide such financial disclosures to SPONSOR or CRO as SPONSOR or CRO may request, on such forms as SPONSOR may supply or as SPONSOR may approve. During the time the Study is being conducted and for one (1) year thereafter, the INVESTIGATOR and each SUBINVESTIGATOR shall update such forms promptly and provide same to SPONSOR as may be requested by SPONSOR or whenever any material change occurs in the information disclosed by a previous form.

9.10 Data Protection

(a) For Studies conducted in India, INSTITUTION and each INVESTIGATOR agree, and shall cause its agents to agree, at all times:

(i) to collect and process all data collected and relating to a Study subject ("Study Data") in accordance with the provisions of this Agreement, each Study Letter or as otherwise instructed by SPONSOR from time to time;

(ii) to comply with all Applicable Law with respect to the processing of Study Data;

(iii) to ensure that they do not collect any data relating to individuals other than the categories of data specified in the relevant Protocols and Study Letters;

(iv) to collect and process Study Data solely for the purposes of a Study and in the manner specified in the relevant Protocol and Study Letter and not to further process such data in any other manner;

(v) not to transfer Study Data collected in the European Economic Area to any person or persons located outside the European Economic Area; provided, however, that INSTITUTION or an INVESTIGATOR may transfer such Study Data in the event that it has received written notice from SPONSOR that such transfer is required or permitted by any Applicable Law or any regulatory or governmental authority;

(vi) to ensure that all Study Data are accurate and, where necessary, kept up to date and to use best efforts to ensure that Study Data which are inaccurate or incomplete are corrected or completed;

(vii) to comply with all written instructions issued by SPONSOR to anonymize the Study Data from time to time:

(viii) to ensure that it notifies SPONSOR promptly (and, in any event, within five days of receipt) of any communication received from a Study subject relating to such subject's rights to access, modify or correct Study Data and to comply with all instructions of SPONSOR in responding to such communications; and

(ix) to ensure that the technical and organizational measures specified in a Protocol and/or Study Letter are taken to protect Study Data against accidental or unlawful destruction or accidental loss or damage, alteration, unauthorized disclosure or access and against all other unauthorized disclosure or access and against all other unauthorized or unlawful forms of processing.

For the avoidance of doubt, all Study Data is Confidential Information hereunder and all of the non-disclosure and non-use obligations set forth in Article 6 shall apply to all Study Data.

INSTITUTION and each INVESTIGATOR agree to comply with its obligations (if any) under Applicable Law to notify any regulatory or governmental authority of its collection and processing activities under this Agreement and further agrees to take all such steps as SPONSOR may reasonably require from time to time in order to enable SPONSOR to comply with any such

notification obligation applicable to SPONSOR.

9.11 COMPLIANCE WITH THE LAWS.

The parties shall comply with all Applicable Laws, including the federal false claims statute (31 USC 3729) and anti-kickback statute (42 U.S.C. 1320a-7(b)) and the related safe harbor regulations and/or their respective equivalent in the country where the Study is conducted.. Accordingly, no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services. Further the parties understand and agree that neither this Agreement nor any consideration paid hereunder is contingent upon INSTITUTION'S use or purchase of any of SPONSOR's products. If any portion of this Agreement is found by any court or agency with jurisdiction over the subject matter hereof not to be in compliance, that portion of the Agreement shall be deemed retroactively amended and reformed as necessary to comply and the parties shall cooperate in taking such action as are necessary and desirable to ensure such compliance.

INSTITUTION agrees that it will not seek or collect, and will not assist the Study Subject in seeking or collecting, reimbursement from any health insurance plan, PPO, or governmental medical plan or other government provided health coverage available to the Study Subject for any medical expenses paid by SPONSOR pursuant to this Agreement.

9.12 INSTITUTION'S ELECTRONIC SYSTEMS

(a) SPONSOR has implemented electronic systems that assist in its analysis of data generated by clinical trials and the submission of such data to regulatory authorities. An important requirement in this process is the ability of the INSTITUTION to electronically enter, review, approve and transmit data. As part of this Study, SPONSOR will, in cooperation with INSTITUTION, evaluate INSTITUTION's electronic equipment and communication capabilities (the "Electronic Systems") to determine if they are sufficient to perform the Protocol and are compatible with SPONSOR's systems. If SPONSOR determines that INSTITUTION's Electronic Systems are either not sufficient to perform the Protocol or incompatible with SPONSOR's systems, SPONSOR will provide INSTITUTION with a laptop computer (the "Computer") and/or hi-speed internet access ("Internet Access", collectively with the Computer, the "Technology"), as applicable.

(b) The Computer shall be the property of SPONSOR. Upon completion of the Study, SPONSOR and INSTITUTION shall make arrangements for the prompt return of the Computer to the SPONSOR. For the duration of the Study INSTITUTION shall (i) take all reasonable steps to maintain the Computer in good operating condition, and (ii) keep the Computer in a secure environment. INSTITUTION shall take such precautions as are necessary to avoid damage or loss to the Computer.

(c) The Computer provided to INSTITUTION will contain all software and operating systems necessary to permit INSTITUTION to perform the Study according to the Protocol and in a manner compatible with SPONSOR's systems. At no time during the term of this Agreement may INSTITUTION install or use any additional software programs on the Computer. Further, INSTITUTION shall neither during the pendancy of this Agreement or thereafter, claim any rights

over such software and operating systems nor permit any third party access to the same, unless permitted in writing by the SPONSOR.

(d) SPONSOR shall provide INSTITUTION with Internet Access for the duration of the Study if deemed necessary for the conduct of the Study. If Internet Access is provided, SPONSOR shall, during the term of the Study, either (i) pay the selected internet service provider directly for such access or (ii) reimburse INSTITUTION for costs actually incurred by INSTITUTION provided such reimbursement is limited to the amount SPONSOR would have paid to the internet service provider had SPONSOR paid internet service provider directly. Upon completion of the Study or expiration or termination of the Agreement, SPONSOR's/CRO's obligation to pay for or reimburse INSTITUTION for such services shall cease and INSTITUTION shall have full and sole liability for such costs. Notwithstanding the foregoing, any costs incurred by INSTITUTION in excess of the basic Internet access fee shall be the sole responsibility of the INSTITUTION.

(e) INSTITUTION may not use the Technology for any purpose other than performance of the obligations required by the Protocol, as set forth in this Agreement and the Protocol. INSTITUTION shall allow only those people directly involved in the conduct of the Study access to the Technology. SPONSOR agrees to provide INSTITUTION with maintenance and repair service for the Technology during the Study. At no time shall INSTITUTION attempt to repair, fix or correct any errors or technical problems related to the Technology.

Shilpi

IN WITNESS WHEREOF, INSTITUTION , SPONSOR and CRO have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

Bristol-Myers Squibb India Private Limited

By: Shilpi

Name: SHILPI SINHA

Title: SR. SITE MANAGER

Date: 23/11/2016

MGM Medical College & Hospital

By:

Name: Dr. A G Shrotri

Title: Dean

Date: 09-11-2016

MGM's Medical College * Aurangabad *

PPD Pharmaceutical Development India Private Limited

By: 21NOV2016

Name: Rashmi Chitgupi
Associate Director - Clinical Management
PPD Pharmaceutical Development India Pvt. Ltd.
01- Dynasty, B-wing (Kanakia Spaces)
Andheri - Kurla Road, Andheri East
Mumbai - 400 059. India.

Title:

Date:

I HAVE READ AND UNDERSTAND THE ABOVE AGREEMENT AND AGREE TO ABIDE BY THE TERMS THEREOF:

Dr. Girish Namdeorao Gadekar (INVESTIGATOR)

DATE 22/09/2016

DR. GIRISH N GADEKAR
D-ORTHO. M.S. (ORTHO)
ASSO. PROF. & HOD
MGM HOSPITAL,AURANGABAD
Reg. No.2001020830

Shilpi

EXHIBIT A

PAYMENT SCHEDULE

CV185-158

TITLE OF STUDY:	"A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total Hip Replacement Surgery"
SPONSOR:	BRISTOL-MYERS SQUIBB COMPANY
INVESTIGATOR:	Dr.Girish Namdeorao Gadekar, Consultant Orthopedician
PAYEE & ADDRESS	Ardent Clinical Research Services Regus, Level-2, Connaught Place, Bund Garden Road Pune, India, 411001

This Payment Schedule includes all costs associated with the conduct of the Study, including, but not limited to, all procedures as presented in the Protocol's Time & Event Schedule; administrative fees; pharmacy fees; laboratory fees; Investigator & Study Coordinator work effort; and overhead costs.

Payment Summary

Payment For All Completed Study Subjects	**INR 1,920,000**

Other Payments

Screen Failure (SF) Payment	same as Screening visit fee
Final Payment	10% of Total Cost Per Subject

Items Paid By Invoice

Symptomatic VTE (PE/DVT) Assessments	Per Invoice
Audio-Video Consenting Equipment	Per Invoice
Unscheduled Visit Payment	Per Invoice
Payment for Recruitment and Retention Activities	Per Invoice
Additional Travel Reimbursement	Per Invoice
IRB Fees	Per Invoice

Payment Details

Subject Care Payment (excludes other payments and invoice-driven payments):

I. **Subject Care** (based on visit driven payments as described below)

a. 30 Subjects X INR 64,000 per Completed Subject = INR 1,920,000

b. **Written permission must be obtained from Sponsor or its designee prior to enrolling additional Study Subjects beyond 30 (thirty)**. The budget will be adjusted for any decrease or agreed-upon increase in the contracted number of Subjects enrolled according to the per Subject cost herein.

c. Payments for Subject care will be made **Quarterly** (i.e. every 90 days) for each Subject visit after source document verification for the visit by Sponsor or its designee for the visits, as noted below.

i. The first quarterly payment will be made 90 days after the First Patient First Visit (FPFV-based on visits occurred and eCRFs completed. Quarterly payments will continue to be generated every 90 days thereafter, provided that eCRFs are received by Sponsor or its designee and there is an amount owed.

ii. Each completed eCRF is noted in TAO as "Save Complete" under the Summary tab. (Note: marking the eCRF as being complete implies that you have met the requirements of the form and consider your responses complete).

iii. Data entry into TAO eCRFs should be completed within **5** business days of a Subject completing each visit.

iv. Queries must be resolved within **5** business days of receipt (both during the Study and after completion of the Study). Queries must be resolved within 48 hours during database lock and interim data cuts.

v. Ten percent (10%) of the amount per visit stated in the visit schedule below will be withheld from each payment. The total withheld amount will be paid pending resolution of all outstanding items as described in the section of the budget titled "Final Payment".

Visit Name	Cost (Rs)
Pre Randomization	15,000
Randomization/Pre Surgery	10,000
Surgery Day 1	6,000
Day 2	6,000
Hospital Discharge	7,000
Day 7 +/- 2 Days	6,000
Day 12 (or Day 35 for THR subj.)	7,000
Follow up Day 42 (or 65 for THR subj.)	7,000
Total Cost Per Completed Patient with 20% OH	64000

All visits above are inclusive of study personnel work effort.

d. For enrolled Subjects who discontinue from the Study early, payments will be made according to the above visit schedule based on Sponsor's or its designee's receipt of completed eCRFs.

Other Payments (Paid by eCRFs, Report, etc.)

II. **Screen Failure Payment**

a. Compensation for Screen Failures will be at the same rate as Screening visit amount per Screen Failure. A Screen Failure is defined as any Subject who signs an Informed Consent Form and completes the screening procedures, but fails to meet the criteria for entry into the next phase of the Study, as set forth in the Protocol.

b. The maximum number of Screen Failures allowed is based on the following table:

Total No. of Subjects Randomized	Number of Screen Failures Paid
0 - 10 Subjects	1
11 - 20 Subjects	2
21 - 30 Subjects	3
31 - 40 Subjects	4
41 - 50 Subjects	5
51 - 60 Subjects	6
61 - 70 Subjects	7
71 - 80 Subjects	8

81 - 90 Subjects	9
91 - 100 Subjects	10

c. All Screen Failure payments will be made upon the completion of the Randomized phase of the Study and based on a Sponsor's or its designee's internal report. As per prevailing service tax regulation, PPD India will not be able to make any payments for screen failures until a service tax valid invoice is received.

III. **Final Payment**

a. The Final Payment will be made upon completion of the last patient, last visit, but only after (1) all eCRFs are completed and have been approved by the Investigator, and submitted to Sponsor or its designee; (2) unused clinical supplies have been returned to Sponsor or its designee, or destroyed on site, or transferred to another Study or Study Site by Sponsor or its designee; (3) the Study Site has duly completed and submitted all required forms and logs reconciling receipt, dispensing, and use and return of the Study drug; and (4) all data queries/questions have been resolved. Final financial reconciliation will occur within 60-90 days after completion of the Study.

b. Final Payment is automatically generated by Sponsor or its designee. As per prevailing service tax regulation, PPD India will not be able to make any payments for final payment until a service tax valid invoice is received.

IV. **Study Drug(s)**

a. All Study Drug(s) will be provided by Sponsor or its designee to the participating Institution.

Items Paid By Invoice

V. **SOC (Standard of Care) and Invoice Requirements**

a. All procedures listed below this section may or may not be considered as SOC (Standard of Care). If for any reason these procedures listed below are not considered SOC at your site, a detailed **Invoice** must be forwarded to the Sponsor or its designee in order to receive payment

b. The Sites must submit detailed **Invoices** to reflect the exact visit where procedures/scans have been performed for Clinical Team's review/approval and for check payment description purposes.

VI. **Symptomatic VTE (PE/DVT) Assessments**

a. If the following Assessments are performed, as required by the Protocol or, as clinically indicated, the Site will be paid at the fixed amounts indicated below upon Sponsor's or its designee's receipt of a clear and itemized invoice:

PROCEDURE	COST (Rs)
CT of Chest/Thorax	33321.60
Pulmonary Ventilation and Perfusion Scan (Lung Scan)	33321.60
Duplex Scan of Lower Extremity arteries (femoral or other) Complete Bilateral Study (B mode Ultrasonography with integrated color flow doppler.	20048.40
Pulmonary Angiogram	2797.92
Venography	39021.75
Complete Extremity Ultrasound	9205.17
Bilateral Extremity Angiography	33321.60
ECG	720.00

VII. **Audio-Video Consenting Equipment**

a. One time charges for Audio-Video consenting equipment up to and not exceeding **INR 50,000** (Rupees fifty thousand only) would be paid to the site upon receipt of invoice. In case the Audio-Video consenting equipment is provided by Sponsor or its designee this amount cannot be claimed by the site.

VIII. **Local Taxes**

a. All payments will be made after deduction of tax at source as applicable and subjected to receipt of original invoices.

b. Service tax as per prevailing government regulation will be applicable on the visit based payment and must be included in a separate, valid invoice.

IX. **Unscheduled Visit Payment**

a. Unscheduled safety visits arising as a result of Subject's participation in the Study will be paid at the maximum rate of **INR 3,625.00** per Subject, per visit.

b. Payments for unscheduled safety visits described above will be made upon Sponsor's or its designee's **receipt of invoice from the Site.**

X. **Additional Travel Reimbursement** ***(For Subjects Traveling over 150 Miles or 240 Kilometers, Round-Trip)***

a. Study-related travel expense for a scheduled Site visit is already included in the total cost per visit. However, for Subjects who may be traveling over 150 miles (240 km) round-trip or more than 75 miles (120 km) each way, the Site may be reimbursed additionally for reasonable travel expenses directly related to the Subject's

participation in the Study (such as air transportation, additional meals, overnight lodging, etc.). The reimbursement amount (per mile/km) will be based on the current IRS' medical-research-rate.

b. In order to be reimbursed for these travel expenses, Sponsor or its designee must receive reasonably detailed invoice(s) (including all supporting documentation or receipts) for actual travel expenses incurred by the Subject.

c. Prior approval from Sponsor or its designee must be secured before allowing any study –related travel expenses for Subjects traveling 150 miles (240 km) round-trip.

XI. Payment and Submission of Invoices

a. Invoice driven payments shall be made within 50 days of receipt of an invoice.

b. All outstanding invoices must be submitted to Sponsor or its designee no later than 50 days of the last patient, last visit at the Site.

c. To avoid delay in payment processing, **all** invoices must contain the following information:

- Invoice Number
- Protocol Number
- Site Number
- Institution Name
- Investigator Name
- Payee Name & Address
- Service tax number of the Institution
- Category of the Service

d. All invoices must be submitted to Sponsor via:

PPD Pharmaceutical Development India Private Limited,
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Andheri East,Mumbai – 400 099

XII. Additional Terms and Conditions:

a. Enrollment/Recruitment will end once this Study's Enrollment/Recruitment goals have been achieved. If the Study is prematurely terminated, the total payment hereunder will be made only for those enrolled/recruited/randomized and evaluable Subjects who were enrolled/recruited/randomized in accordance with the above fee schedule for Study visits completed at the time of the termination notice and upon receipt of completed eCRFs by Sponsor or its designee. Payee agrees to refund any excess amount previously paid, and Sponsor agrees to pay any amount owed based

on the receipt of acceptable eCRFs by Sponsor or its designee along with the resolution of all queries/questions relating to the Study.

b. No additional funding requests will be considered without the prior written consent of Sponsor or its designee.

APPENDIX B

PPD

Payment Authorisation Form for Vendors

To be completed by the investigator or payee

All fields are **mandatory** unless indicated otherwise

NB **IF YOU HAVE COMPLETED THIS FORM BEFORE, YOU NEED ONLY COMPLETE IT AGAIN IF ANY OF YOUR DETAILS HAVE CHANGED**

Payee or Investigator Details

Description (CTMS Field) (Finance Field)	**Payee or Investigator Information**	Max Chars for Finance Field Incl. Spaces
Payee Name *(in terms of the provisions of the Statement of Agreement):*	**Ardent Clinical Research Services**	80
(To whom should the cheque or transfer be made payable to?) **N.B. This must be the exact payee as it appears on the bank account**		
Street Address of Payee (Address Line 1) (Address 1)	**Regus, Level-2**	30
Department Name (if applicable): (Address Line 2) (Address 2)	**Connaught Place**	30
Room / Floor (if applicable) (Address Line 3) (Address 3)	**Bund Garden Road**	30
Other Address Details (if applic.) (Address Line 4) (Address 4)	**Pune**	30
Country (Country) (Country)	**India**	2 *ISO Code*
State / Province (if Applicable) (State / Province) (State or Province)	**Maharashtra**	2
Town/City (City) (City or Address 5)	**Pune**	18
Postal Code (Zip/Postal Code) (Postal Code)	**411001**	10
Contact name for payee if different from above	**Mr. Chandu Devanpally**	30
Telephone	**09545817447**	27
Fax		27

E-mail	**cdevanpally@ardent-cro.com**	60
Web page	**www.ardent-cro.com**	60

Service / VAT / Tax Withholding Details

(Please note that payments cannot be made without these fields being completed):

Service / VAT / Sales Tax

Are you Service Tax / VAT / Sales Tax registered?	**YES**		*Delete where applicable*

If **YES**, please provide the following information

Service Tax / VAT number, if known	**APQPD7081MSD001**
At what % rate will Services Tax / VAT / Sales Tax be charged?	**15% or as applicable**

Tax Withholding

Is PPD required to withhold Tax from Payments?	**YES**		*Delete where applicable*

If **YES**, please provide the following information

PAN ID number Please provide a copy of the PAN Card. In case you are exempt from TDS please provide IT certificate	APQPD7081M

Payment Method required

What is your preferred payment method?	**Cheque**		*Delete where applicable*

If **Bank Transfer**, please complete the following details:

Preferred

IBAN Number	
BIC Number	

Or

PPD

APPENDIX B

Payment Authorisation Form for Vendors

To be completed by the investigator or payee

Bank Account Number	**50200007013912**		
Sorting Code *(For UK only)*		**Branch number/Bank code**	
RTGS/NEFT code:	**HDFC0000825**		

Bank Details

Bank name:	**HDFC Bank**		
Address:	SUVIDHA RESIDENCY, UNIT NO 101,102 SHOP NO 1,2,AND 3,HISSA NO 5/1 TO 5/6,PLOT NO 1,HINGRE KHURD PUNE MAHARASHTRA		
City	**Pune**	**Postal Code**	**411051**
Country:	**India**	**Private or Public Bank Account:** *(Belgium and France only)*	

Declaration

I have provided the above details and confirm they are correct:

Investigator/Institutional Signatory	
Name in print	DR GIRISH N. GADEKAR
Date (dd/mmm/yyyy)	22/09/2016

TO BE COMPLETED BY THE PPD CRA/CONTRACT SPECIALIST

Other Financial Data

PPD CRA/CONTRACT SPECIALIST name	**Kathrine Joy**
Location	**Mumbai**
Paying Country *(if in doubt, contact the Financial Analyst for the study)*	**India**
In what currency is the Statement of Agreement defined	**INR**

CASCADE Interface Data

- If the Investigator is the payee, please enter the CASCADE **Contact** number.
- If the Hospital/R&D etc is the payee, please enter the CASCADE **Account** number.
- It may be that the Payee listed above already has a Vendor number (Contact/Account Screen and More Info View) and Remittance code (Contact/Account Screen and Addresses View).
- Please note that these fields are crucial to correct payments being made. Please confirm the correct numbers with your CASCADE Super User or the cascade business support team via the helpdesk.

NOTE: DO NOT USE THE CTMS SITE NUMBER HERE

CTMS Number *Contact/Account – More Info View*	**Vendor Number** *Contact/Account – Addresses View*	**Remittance Code** *Contact/Account – Addresses View*

If the Account or Contact has a vendor number, please identify the purpose of this form, if you are **certain** of the correct option.

New Vendor	☐	Amend Vendor	☐	New Remittance Address Required	☐	Amend Remittance Address	☐

Lawson Data

TO BE COMPLETED BY PPD FINANCE DEPARTMENT

Vendor Name ***(used in Lawson)***			
Vendor Number:		**Vendor Location**	
Vendor Group		**Distribution Code**	
Vendor Class	INV	**Separate Payment**	Y
Search Name ***(used in LAWSON):***			
Tax Code ***(dependent on Service Tax / VAT Reg)***			
Cash Code ***(dependent on country and currency)***			
Payment Code ***(dependent on method of payment)***			
Next Available User Field ***(AP10.1)***	CTMS		

Financial Agreement for Clinical Trial

This "Financial Grant" dated as of the 22nd November 2016 is by and between **"Clinsearch Healthcare Solutions Pvt. Ltd" ("CRO"),** having its office at 401, 4th Floor, Commercial Building no. 3, Highland Arcade (Park), Behind 'D' Mart, Kolshet Road, Off. Ghodbunder Road, Dhokali, Thane (W), Mumbai 400 607 and **Dr. Hemangi Rajiv Jerajani (MD,DVD, FIAD) MGM Medical College & Hospital Sector 18, Kamothe, Navi Mumbai, India-410209**

(Trial Site) to conduct following study entitled:

"Real World, Non-Intervention, Observational Study of Hydroxyzine hydrochloride in Chronic Pruritus"

DEFINITIONS

1. A "qualified patient / subject" is a participant in the study who, on entrance into the treatment phase of the study, met all of the inclusion criteria and none of the exclusion criteria in the Protocol and who gave his or her written informed consent to participate.
2. "Completion" of a patient / Subject's participation means a qualified patient / subject has completed the study and met the compliance standard in the protocol required to permit evaluation and that the patient/subject's Case Record Form has been completed by the Investigator and accepted as satisfactory by Sponsor.
3. A "withdrawn" participant is a qualified patient/ subject who was withdrawn from the study because of treatment failure or adverse event but otherwise met the compliance standard with the Protocol.

ENROLLMENT

Enroll 60 patients thereby having the patients completed at the end of the study.

AMOUNT

Sponsor is furnishing research grant of **Rs. 2,10,000 (Two Lakh Ten Thousand Rupees Only)** for completion of Sixty patients (Rs.700/- per completed visits) for the study, payable upon receipt of appropriate documents from your end (see Annexure 1 for Mode of payment). This payment is for all scheduled and approved visits or procedures for the following activities –

i. Site Feasibility
ii. Obtaining EC approval
iii. Site Initiation
iv. Subject Enrollment, follow up
v. Monitoring
vi. Close-Out
vii. Source document maintenance

MEDICAL COLLEGE * NEW MUMBAI 410209 * KAMOTHE

Dean
MGM Medical College, Navi Mumbai
Dean.
M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

viii. Case Report Form Completion
ix. AE, SAE reporting, follow up
x. Query resolution
xi. Study Updates to CRO/Sponsor
xii. Review of Clinical Study Report
xiii. Laboratory reports, Photographs review
xiv. Audit If any

Study timelines

Initiation : 30th October. 2016
Completion : 30th June. 2017
Agreed by -

Signature: H. Rajrajani

Name: **Dr. Hemangi Rajiv Jerajani**
Address: **MGM Medical College & Hospital**
Sector 18, Kamothe
Navi Mumbai, India-410209

Cheque in favor of:

1. **For Research Grant:** MGM Institute of Health Science

PAN No: 04 AACTM0014C

Signature: for,

Name: **Dr. Deepak Langade,** Director
Address: Clinsearch Healthcare Solutions Pvt. Ltd.
401, 4th floor, Commercial Bldg. No. 3,
Highland Arcade (Park), Behind 'D' Mart,
Kolshet Road, Off. Ghodbunder Road,
Dhokali, Thane (w) 400607, Maharashtra, India.,

Date: 25 February 2017.

CLINSEARCH
Healthcare Solutions Pvt. Ltd.

Annexure-1

Mode of Payment

Research Grant	Total ` 3500 per patient Total no. of subjects: 60 subjects Grand Total: 210,000/-	
First disbursement	Upfront on signing contract	17,500/-
Second disbursement	On enrollment of 20 patients	17,500/-
Third disbursement	On completion of 20 patients	17,500/-
Fourth disbursement	On enrollment of 40 patients	39,375/-
Fifth disbursement	On enrollment of 60 patients	39,375/-
Sixth disbursements	On completion of 60 patients	39,375/-
Final disbursement	Signing the Clinical study report	39,375/-

Note:

1. In an event of any additional subjects enrolled as per need and after approval of CRO, the additional payment would be made @ `3500/- per completed subject
2. In the event of less no. of subjects being enrolled, payment would be made @ 3,300/- per completed subject
3. In an event of Lost to follow up of subjects, payment would be made @1,750/- per subject.

H. K. Jerraj Rao

Financial Agreement for Clinical Trial

This "Financial Grant" dated as of the 22nd November 2016 is by and between **"Clinsearch Healthcare Solutions Pvt. Ltd" ("CRO"),** having its office at 401, 4th Floor, Commercial Building no. 3, Highland Arcade (Park), Behind 'D' Mart, Kolshet Road, Off. Ghodbunder Road, Dhokali, Thane (W), Mumbai 400 607 and **Dr. Hemangi Rajiv Jerajani (MD,DVD, FIAD) MGM Medical College & Hospital Sector 18, Kamothe, Navi Mumbai, India-410209**

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i. Site Feasibility
ii. Obtaining EC approval
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iv. Subject Enrollment, follow up
v. Monitoring
vi. Close-Out
vii. Source document maintenance

Dean
MGM Medical College, Navi Mumbai
Dean.
M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

viii. Case Report Form Completion
ix. AE, SAE reporting, follow up
x. Query resolution
xi. Study Updates to CRO/Sponsor
xii. Review of Clinical Study Report
xiii. Laboratory reports, Photographs review
xiv. Audit If any

Study timelines

Initiation : 30th October. 2016
Completion : 30th June. 2017
Agreed by -

Signature: H. Rajrajani

Name: **Dr. Hemangi Rajiv Jerajani**
Address: **MGM Medical College & Hospital**
Sector 18, Kamothe
Navi Mumbai, India-410209

Cheque in favor of:

1. **For Research Grant:** MGM Institute of Health Science

PAN No: 04 AACTM0014C

Signature: for,

Name: **Dr. Deepak Langade,** Director
Address: Clinsearch Healthcare Solutions Pvt. Ltd.
401, 4th floor, Commercial Bldg. No. 3,
Highland Arcade (Park), Behind 'D' Mart,
Kolshet Road, Off. Ghodbunder Road,
Dhokali, Thane (w) 400607, Maharashtra, India.,

Date: 25 February 2017.

CLINSEARCH
Healthcare Solutions Pvt. Ltd.

Annexure-1

Mode of Payment

Research Grant	Total ` 3500 per patient Total no. of subjects: 60 subjects Grand Total: 210,000/-	
First disbursement	Upfront on signing contract	17,500/-
Second disbursement	On enrollment of 20 patients	17,500/-
Third disbursement	On completion of 20 patients	17,500/-
Fourth disbursement	On enrollment of 40 patients	39,375/-
Fifth disbursement	On enrollment of 60 patients	39,375/-
Sixth disbursements	On completion of 60 patients	39,375/-
Final disbursement	Signing the Clinical study report	39,375/-

Note:

1. In an event of any additional subjects enrolled as per need and after approval of CRO, the additional payment would be made @ `3500/- per completed subject
2. In the event of less no. of subjects being enrolled, payment would be made @ 3,300/- per completed subject
3. In an event of Lost to follow up of subjects, payment would be made @1,750/- per subject.

H. K. Jerraj Rao

State Bank Of India, Polytechnic Branch, AHMEDABAD

भारत 45324 SPECIAL ADHESIVE गुजरात
169217 JAN 12 2016
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GUJARAT STAMP DUTY Rs.0000100/-PB5576
INDIA

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 12 Day of Jan 2016 by and between,

Veeda Clinical Research Pvt. Ltd, an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Chandrasekhar Tamane ("Principal Investigator"), having its place of work at **MGM Medical College & hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra.**

And

MGM Medical College & hospital ("Institution") having its principal place of business at **N-6 CIDCO, Aurangabad 431003, Maharashtra.** (Hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Biocon Limited, SEZ unit, Biocon Special Economic Zone, Plot No.2&3, Phase IV- B.I.A, Bommasandra-Jigani Link Road, Bangalore - 560099, India (herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 15-VIN-155 entitled " A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Limited, India vs. Afinitor® (Everolimus) tablets, 10 mg of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients."; and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement excluding subject medical records. Data shall be the sole and exclusive

MGM's Medical College Aurangabad

Veeda Clinical Research Ahmedabad

property of Sponsor and may be freely utilized by Sponsor and their representatives. Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.

- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Council for Harmonization, Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
- "IEC" means the Independent Ethics Committee/Institutional Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Everolimus tablets, 10 mg of Biocon Limited, SEZ unit, Biocon Special Economic Zone, Plot No.2&3, Phase IV- B.I.A, Bommasandra-Jigani Link Road, Bangalore - 560099,India an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

2.2 Conduct of Study Principal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be limited to, the

following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of Investigator(s) and sub-Investigator(s), confirmation of adequate site facilities, etc.);
b) Progress reporting (including recruitment figures) to Ethics Committee and Veeda on a regular basis;
c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;
d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Veeda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.
e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
f) Inform the Ethics Committee of study closure;
g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;
h) Handling and storage of compound according to protocol; and
i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.
j) The Principal Investigator is responsible for training and supervision of sub-Investigators and other site study team member on the procedures specified in the Protocol to ensure scientific, technical, and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGI), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

In case of SAE other than death the investigator will send the detailed report within 10 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 10 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorized facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Investigational Medicinal Product i.e. both unused and retention samples will be retained at the site after completion of the study for a desired period, as per USFDA/sponsor requirement and also as per the written instruction given by Veeda/Sponsor at free of cost. The samples will be retained for a period of at-least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not

approved, at-least 5 years following the date of completion of bioavailability study in which the sample from which the reserve sample was obtained was used. Investigational Medicinal Product i.e. both unused and retention samples will continue to remain at the site unless further information is received from Veeda/Sponsor.

2.3.11 Principal Investigator/ Institute will intimate to CRO and Sponsor about any inspection/s from any regulatory authorities for the study, within 48 business hours of their notification.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written notice. Principal Investigator shall submit written reports, as directed *by* Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda

designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigator and Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five (45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".
The "Per Subject Fee" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:
    - all study related activities such as conduct of visits and Source & CRF completion
    - time and effort of Principle Investigator and other site staff

- study coordinator salary
- all diagnostic tests and other investigations (ECG, X-ray Chest etc)
- housing or hospital stay for patients including meals
- Patient conveyance/compensation
- miscellaneous (telephone, fax, courier, etc)
- all overhead costs

b) A complete and evaluable patient is defined as follows:
   - all procedures must be performed according to the protocol
   - a patient will only be included according to the inclusion/exclusion criteria
   - all data are documented accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.
   - Name of Ethics Committee: **MGM Ethics Committee for Research on Human Subjects**
   - Relationship between the site/institution and Ethics committee: **Institutional Ethics Committee**
   - Ethics committee payee name: **MGM Medical College, Aurangabad**
   - Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **NA**
   - PAN no. of the payee: **AAATM4256E**
   - Ethics Committee Fees: Rs. **(Excluding TDS): INR 40000/-**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, X-ray Chest, and SAE or in case patient withdrew consent.

h) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will manage SAE reimbursement for medical management expenses towards AE/SAE directly to the patient or LAR and SAE compensation payment directly to the patient / LAR with prior written approval from the sponsor and will get for reimbursement for those expenses.

k) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enrol any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.
   Details of Payee are:

Name of Payee: MGM Medical College, Aurangabad
PAN No. : AAATM4256E

MGM's Medical College Aurangabad

Veeda Clinical Research Ahmedabad

Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts. The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of 2 months however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 1 month from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 10 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: MGM Medical College, N-6 CIDCO, Aurangabad. 431003. Maharashtra. INDIA

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator /

Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form

approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded through audio-visual means.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorised on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created hereunder for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed

publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after

termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Not withstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program. Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be

transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:
Veeda Clinical Research Pvt. Ltd.
Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.
Attention: Dr. E. Venu Madhav
Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:
Name: **Dr. Chandrashekhar Tamane**
Address: MGM Medical College & hospital, N-6 CIDCO, Aurangabad – 431003, Maharashtra

Attention:
Phone: +91- 9561707496
Fax: NA

If to Institution:
Name: Dr. A G Shroff
Designation: Dean
Address: MGM Medical College & hospital, N-6 CIDCO, Aurangabad – 431003, Maharashtra

Attention:
Phone: +91-240-6601100
Fax: +91-240-2487727

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services hereunder, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of

this Agreement.

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

MGM's Medical College Aurangabad

Vedic Clinical Research

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 12 Jan 2016

For, Principle Investigator

Name: Dr. Chandrashekhar Tamane
Title: Principle Investigator

Date: 01 Mar 2016

For, Institute

Name: Dr A G Shroff
Title: Dean, MGM Medical College, Aurangabad

Date: 01-03-2016

Witness:

Name: Dr Lunjamanshi Pravin.
Contact Details: 9764994449.

SCHEDULE "A"

PROTOCOL

TITLE:

"A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Limited, India vs. Afinitor® (Everolimus) tablets, 10 mg of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients."

SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

Screen failure will be paid an amount of 5,000 INR respectively.

a) Trial Budget

Visit	Visit 1 (Screening)	Visit 2 (Day 0/1)	Visit 3 (Day 6±1)	Visit 4 (Day 11/12/13/14/15)	Visit 5 (Day 20±1)	Visit 6 (Day 25/26/27/28/29)	Sub-total
Study Team Grant							
Principal Investigator Grant	3,000.00	2,500.00	2,500.00	12,000.00	2,500.00	12,000.00	34,500.00
Study coordinator grant	1,000.00	1,000.00	1,000.00	5,000.00	1,000.00	5,000.00	14,000.00
Phlebotomy Charges*	200.00	200.00	-	2,000.00	-	2,000.00	4,400.00
Study Assessment Grant							
Urine Pregnancy Test and Urine Drug screen test	-	100.00		100.00		100.00	300.00
ECG	400.00	-				400.00	800.00
X-ray	350.00	-					350.00
Stationary, Phone, Courier and Fax charge	150	150	150	300	150	300	1,200.00
Hospitalization & Meal Charges	-	3,000.00		12,000.00		12,000.00	27,000.00
Sub-total	**5,100.00**	**6,950.00**	**3,650.00**	**31,400.00**	**3,650.00**	**31,800.00**	**82,550.00**
Institutional Overhead (20%)	**1,020.00**	**1,390.00**	**730.00**	**6,280.00**	**730.00**	**6,360.00**	**16,510.00**
Total							**99,060.00**
Service Tax (14%)							**13,868.40**
Total Grant							**112,928.40**
Patient Compensation	1,000.00	2,000.00	1,000.00	5,000.00	1,000.00	5,000.00	**15,000.00**
* Phlebotomy charges for PK sampling will be paid only if site phlebotomist is used.							

MGM's Medical College Aurangabad

Veda Clinical Research Ahmedabad

Taxes:

- All payments shall be made to the Principle Investigator / Institution / any other payee party as defined in the agreement, after deducting of withholding tax (TDS) as applicable from time to time as per the Income tax act. The TDS certificates for the withholding tax will be provided at the end of the financial year.

- Patient compensation will be treated as a reimbursement and TDS will be not deducted from the patient compensation subject to production of original bills and supporting documents (signed by patient) without any mark up by the Principle Investigator and Institution.

CLINICAL STUDY AGREEMENT

This clinical study agreement(**"Agreement"**) is executed as of this the 9th day of Aug 2016 **(Effective Date)**by and between:

Sun Pharma Advanced Research Company Ltd.(CINL73100GJ2006PLC047837),a company registered under the Companies Act, 1956 having its registered office at SPARC Ltd, Akota Road, Akota, Vadodara - 390020 India and having a business address at 17/B, Mahakali Caves Road, Andheri East, Mumbai 400093, India, which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the **"Sponsor"**).

AND

Mahatma Gandhi Mission's Medical College & Hospital ,a hospital having its registered office at N-6 CIDCO, Aurangabad-431 003, Maharashtra, India, which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**").

AND

Dr. Chandrashekhar Tamane, MBBS, MD (Oncology), Principal Investigator, at Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad-431 003, Maharashtra, India (hereinafter referred as the **"Investigator"**)

(each a "Party" and collectively, the "Parties")

WHEREAS:

A. The Institution is a health care and research organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;

B. Sponsor is a pharmaceutical company involved, inter alia, in the research, development and manufacture of medicines for use in humans and has developed **Paclitaxel Injection Concentrate for Nano-dispersion (PICN)** which is intended to be used for treatment of **locally recurrent or metastatic breast cancer**. Sponsor represents that it has applied for the necessary permissions and licenses required under the provisions of relevant Acts and Rules which are required for use of the same on subjects/ healthy human volunteers etc.

C. Sponsor desires Institution to study **the bioavailability and bioequivalence of PICN** and Institution is willing to perform a clinical study of the Investigational Product (IP).

NOW THEREFORE in consideration of the promises and mutual covenants herein contained, Parties hereby agree as follows:

H.D.F.C. Bank, Andheri Branch. Trade star Building, J.B.Nagar Andheri (E), Mumbai-400059

D-5/STP/V/R.1104/04/2005

भारत 61298 Special Adhesive 186563 AUG 09 2016 महाराष्ट्र

Rs.60001001-PB514 STAMP DUTY MAHARASHTRA

1. SCOPE

1.1 The Study is of mutual interest and benefit to Sponsor and Institution, and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.

1.2 The Institution shall exercise its best efforts to carry out the research ("**Study**") set forth in the Protocol **CLR_16_13: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And Abraxane® In Subjects With Locally Recurrent Or Metastatic Breast Cancer**,which has been provided prior to signing of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. The Study shall be conducted under the direction of Investigator in accordance with this Agreement, subject to review and prior approval by the institution's ethical committee.

2. CONDUCT OF THE CLINICAL TRIAL

2.1 The Investigator and the Institution shall conduct the Study in accordance with the Protocol. The Sponsor is responsible for obtaining and maintaining all applicable regulatory approvals for the Study in India. The Sponsor, Investigator and Institution shall perform the Clinical Study in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945 : Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

2.2 It is explicitly agreed and acknowledged by the Parties that the Protocol for clinical trial/Study be reviewed and approved by the Ethical Committee ("EC") registered with DCGI before the commencement of the Study. The Investigator shall obtain and deliver a copy of such approval to the Sponsor. The approval must indicate the date of issuance and bear the name and signature of the Chairperson or Secretary of the EC. If any such committee do not exist in the Institution, then the approval granted to a protocol by the ethics committee of another institution will be applicable to use of that protocol in the Institution.

2.3 The Institution and Investigator agree that the Sponsor or its designee as clinical monitor will conduct routine monitoring visits at mutually convenient times and upon reasonable advance notice to the Investigator. The clinical monitor will have direct access to all original records and documents pertaining to the study to ensure that the study is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement. Similarly, sponsor may conduct audit at mutually convenient times and upon reasonable advance notice to the Investigator. The auditor will have direct access to all records and documents pertaining to the study.

2.4 It is explicitly agreed and acknowledged by the Parties that in case Investigator is unable to perform the study in accordance with this agreement, the Institution shall appoint another Investigator in consultation with the Sponsor. The Institution shall take

written consent from the Sponsor prior to such appointment. The Sponsor retains the right to suggest Investigator(s) for appointment to conduct and perform the Study.

2.5 If any biological samples are to be tested as part of the Study, these are to be tested in accordance with the Protocol and at a central laboratory approved by Sponsor and with the Clinical Trial Subject's signed written informed consent form. If study requires local lab, the investigator would share applicable documents (viz. lab head CV, accreditation, Lab normal values)It is explicitly agreed and acknowledged by the Parties that Collection, Retention, Use and Destruction of Biological Samples by Institution or Investigator or Sponsor or either of the parties shall be in accordance with the applicable Protocol, acceptable clinical trial practices, applicable subject privacy and informed consent laws and in compliance with all applicable laws and regulations.

For the investigations required to be conducted at the local laboratory, the expenses will be reimbursed as per actuals, subject to submission of the original invoices and corresponding receipts for the same obliterating subject's identity.

3. OBLIGATIONS, REPRESENTATIONS & WARRANTIES OF THE PARTIES

3.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the appropriate EC for the conduct of the clinical Study and from time to time the Investigator shall inform Sponsor about the progress of EC submissions, and provide Sponsor and the Institution with all correspondences relating to such submissions. The institution shall ensure the proper conduct of Study.

3.2 The Investigator shall be responsible for obtaining a signed informed consent form from each Clinical Study Subject prior to the Clinical Study Subject's participation in the Clinical Study.For clarity **"Clinical Trial Subject"** means a person recruited to participate in the Clinical Trial. The investigator shall comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles in obtaining and documenting informed consent. The Parties agree that in addition to the requirement of obtaining written informed consent, , including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality.As per applicable regulatory requirement, it is agreed and acknowledged by the Parties that in case of certain clinical trials, audio-video recording of the informed consent process to be maintained by the investigator for certain subjects. In such event, the Parties will agree the necessary terms and conditions relating to the audio-video recording and incorporate the same in the informed consent form.

3.3 In addition,prior to the beginning of the Study, the Investigator must have the EC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to Clinical Trial Subject. Neither the investigator, nor the trial staff, should coerce or unduly influence a Clinical Trial subject to participate or to continue to participate in a trial.

It is agreed and acknowledged by the Investigator and the Institution that when a clinical trial (therapeutic or non-therapeutic) includes Clinical Trial Subjects who can only be enrolled in the trial with the consent of the Clinical Trial Subject's legally acceptable representative (e.g., minors, or subjects with severe dementia), the Clinical Trial

Subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

3.3 The Investigator shall take reasonable efforts to recruit the agreed number of Clinical Trial Subjects on a timely basis and the Parties shall take reasonable efforts to conduct the Clinical Study in accordance with the agreed time period.

Investigator shall target to enroll (randomize) **6-8 subjects** in the study.

3.4 The Institution and Investigator shall not permit the use of IP for any purpose (whether directly or indirectly) other than the conduct of the clinical Study and upon termination or completion of study, all used and unused IP shall, at Sponsor's instructions, either be returned to Sponsor or destroyed in accordance with the Protocol or Sponsor's written instructions.

3.5 It is explicitly agreed and acknowledged by the Parties that the Study may involve the participation of multiple sites and recruitment and in such event, when the enrolment goal for the clinical Study as a whole is reached, enrolment will be closed at all sites, including the trial Site, regardless of whether the Institution has reached its individual enrolment goal.

3.6 To the extent permitted by law, the Institution and the Investigator shall immediately inform Sponsor of:

3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or

3.6.2 any queries by State or Central Information Commission under Right to Information Act (amended up to date)

In connection with the clinical Study and forward promptly to Sponsor copies of any correspondence from any such authority.

The Institution or Investigator shall use its best efforts to obtain the approval of the regulatory authority (e.g. DCGI or state FDA personnel) to have a representative of Sponsor present during any such visit. If a representative of Sponsor is unable to be present during a visit, the Institution and the Investigator shall provide Sponsor with a prompt brief summary followed by a detailed written report following the visit.

3.7 The Institution and the Principal Investigator shall keep complete and accurate records of the conduct of the clinical Study and of all clinical Study data in accordance with generally accepted industry standards and practices and applicable Law. The Institution and the Investigator agree to retain all such recordsfor a period of not less than fifteen (15) years from the date of completion of Study or termination of this Agreement, whichever is earlier,or any such period prescribed in the Sponsor's 'Document Retention & Destruction Policy'(the "Retention Period"). The Institution shall use reasonable efforts to give Sponsor written notice before destroying the Clinical trial documentation and clinical trial data. Any such destruction is subject to prior written consent of the Sponsor. In case, Institution and Principal Investigator do not have archival facility as per Sponsor's

expectations, Institution and Principal Investigator agree tothird party archival facilitated by the sponsor respecting confidentiality of subject's data.

For clinical/ therapeutic bioequivalence study, the investigator and institution agree to retention of Investigational Product (IP) as per regulatory requirements. In case, Institution and Principal Investigator do not have archival facility for IP as per Sponsor's expectations, Institution and Principal Investigator agree to third party archival by the sponsor respecting confidentiality of subject's data.

3.8 The Investigator undertakes to document all Adverse Events (AE) on adverse event page of Case Report Form (CRF). The investigator shall report all serious adverse events (SAE) to the licensing authority (DCGI), sponsor/ CRO (if applicable) and chairperson of ethics committee within 24 hour of SAE occurrence. The investigator shall report all SAE after due analysis to the licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. In case, Investigator fails to report any SAE within stipulated period, the investigator shall have to furnish the reason for the delay to the satisfaction of licensing authority along with the report of SAE. Sponsor's safety physician/ CRO (if applicable) shall report all SAE after due analysis to licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. Sponsor's safety physician/ CRO (if applicable) shall report all serious adverse events to other participating Investigators within the timelines as per the applicable regulatory requirement. (this shall be for multicentric studies). Sponsor's safety physician/ CRO (if applicable) shall notify SAE to other regulatory authorities as applicable.

As much information as possible shall be supplied by Investigator at the time of the initial report with at least the following information using SAE Report Form.

- Name, address, and telephone number of the reporting Investigator.
- Investigational product(s).
- Protocol number.
- Subject identification number, initials, sex and date of birth.
- Description of the AE, reason considered serious, measures taken and outcome (if resolved.
- Likelihood of drug causation of the adverse event assessed by the Investigator.

A SAE is any untoward medical occurrence that, at any dose:

- results in death;
- is life-threatening;
- requires in-subject hospitalization or prolongation of existing hospitalization; [For the avoidance of doubt, A planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious

deterioration in health or if the hospitalization is clearly not associated with an AE [(e.g., social hospitalization) are not to be considered as SAEs.]

- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect;
- important medical event.

For the sake of clarity, the term "life-threatening" in the definition of "serious" refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event, which, hypothetically, might have caused death if it were more severe.

To the maximum extent permissible under applicable laws and DCGI regulation, the Sponsor shall pay all medical expenses pertaining to Study subject in the event of any AE or SAE. In case of trial related injury or death, the financial compensation will be paid to the subject/ nominee subject to the terms and conditions of this Agreement.

3.9 The Sponsor shall pay all medical management pertaining to Study subject in the event of any SAE, and any IP or study participation related AE, unless it has arisen due to non-adherence to the terms of the Protocol or Sponsor's written instructions on IP as agreed by Investigator ECand/or the same has resulted from the negligence or willful malfeasance or malpractices by Investigator and /or any trial staff or the Institution.

If Subject has a medical emergency, illness or injury that was caused by the research drug or study procedures, Sponsor will provide subject medical management as per the applicable regulatory requirement.

In case of Study related injury or death, to the maximum extent permissible under applicable laws and DCGI regulation, Sponsor will provide complete medical care along with compensation for the injury or death. In case of any SAEs (death and other than death) EC will evaluate and give its opinion regarding compensation to DCGI. Subject will get an additional compensationwill be over and above any expenses incurred on subject's medical management from Sponsor if recommended by DCGI. Subject or his/her nominee(s) has the right to contact the Sponsor or his representative, for the purpose of making claim in the case of trial related injury or death.

3.10 Investigator warrants and represents that:

3.10.1 he is free to participate in the clinical trial/ Study and there are no rights, which may be exercised by, or obligations owed to any third party, which might prevent or restrict his performance of the obligations detailed in this Agreement;

3.10.2 where the Institution is not the Investigator's principal employer, he has notified his principal employer of his proposed participation in the clinical trial/Study and, where relevant, his supervision of trial site team members. He has obtained all necessary consents from his principal employer relating to this;

3.10.3 He is not involved in any regulatory or misconduct litigation or investigation by the Drugs Controller General of India, Food and Drug Administration, the Ministry of Health, or other regulatory authorities;

3.10.4 He is qualified to provide clinical Study services based on the skills and experienceand has reviewed information regarding the Sponsor's IP and the Protocol for the proposed clinical Study and wishes to conduct the trial and to supervise the team members at the trial site; and

3.10.5 During the Clinical Trial, he will not serve as an investigator or other significant participant in any clinical trial/study for another sponsor or any CRO companies if such activity might adversely affect his ability to perform his obligations under this Agreement.

3.11 Institution certifies that neither Institution nor any person (including Investigator) employed or engaged by Institution in the conduct of the Study has been debarred pursuant to applicable provisions of law (whether state or central) and that no debarred person will in the future be employed or engaged by Institution in connection with conduct of the Study. Institution further certifies that it will notify Sponsor immediately in the event of any debarment or threat of debarment of any person employed or engaged by Institution in the conduct of the Study occurring during the period of this Agreement.

3.12 Sponsor, Institution and the Investigator represent and warrant that it has the right to enter into and fully perform this Agreement and, by entering into this Agreement it is not in violation of any law, statute, agreement or any other statue.

4. FINANCIAL ARRANGEMENTS

4.1 SPARC, as Sponsor, has agreed to provide financial support for the project. The Sponsor shall pay fees for the services of the Investigator in accordance with the budget as per **Exhibit-A.**

4.2 Sponsor shall make payments to Institution in accordance with the payment schedule set forth in Exhibit A and incorporated herein. Cheque(s) shall be made payable and sent to the:

Payee Name: MGM Medical College
PAN: AAATM4256E

4.3 The Investigator agrees to make every effort to supervise and lead the study to completion as planned and in time. Should any circumstances beyond his control delay the project or make it impossible to complete it, the Investigator shall give due notice to the Sponsor so as to minimize the overall project delay or the loss, and return funds to the sponsor on pro rata basis as per Exhibit A. The Investigator and Institution should facilitate return of unused IP to sponsor or other site as per sponsor's instructions.

4.4 The Institution shall raise invoice on the Sponsor and separately specify Service Tax payable, if applicable on the services rendered and shall also show other necessary details such as Service Tax registration no. etc. so as to enable Sponsor to claim credit for the same as per law. The Sponsor shall verify the invoice and make the payment within 30 days from the receipt of the invoice submitted by Institution. However, if, upon verification by Sponsor, the invoice is found to be incorrect or inappropriate, the same shall be returned by

Sponsor to the Institution for correction and revision. No other costs, payments and expenses would be borne by Sponsor unless specifically mentioned in this agreementor mutually agreed in writing in advance. Notwithstanding the foregoing, any payment under this Agreement is subject to deduction of applicable Tax-deduction-at-source (TDS). Sponsor shall deduct the amount and pay balance amount to the Institution.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective Date and will continue for a period of 5 years from the Effective Date or upon completion of the Clinical Study, which ever is earlier.

5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. Not with standing to the above, the Investigator may terminate the Study, if the Investigator suspects an adverse drug reaction / adverse drug event related to the Study related procedure and of serious nature to take its cognizance, after informing Institution, EC and Sponsor in writing. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by Sponsor to Principal Investigator, Institution or any other person under this agreement.

5.3 Sponsor may terminate this Agreement upon thirty (30) days prior written notice to the Institution and the Principal Investigator, or such shorter notice period as required by a Regulatory Authority (whether State or Central), for any reason whatsoever.

5.4 Without limiting the generality of the foregoing, Sponsor may terminate this Agreement :

5.4.1 if the Investigator is not performing the Study as required in the protocol;

5.4.2 in case of failure of the Investigator and/ or Institution to provide access by Sponsor representatives /Clinical monitor all original medical records necessary to verify entries on study case report forms;

5.4.3 in case of an unauthorized replacement of Investigator;

5.4.4if Sponsor determine that business or scientific considerations require termination of this Agreement (either full or in part);

5.4.5 if Case report forms provided to Investigator by Sponsor for use in the study are not legibly and/or accurately completed and forwarded the same to Sponsor or its designated representative persistently within 1 week of each Subject's visit date; or

5.4.6 if any malpractices adopted either by Investigator or Institution or both.

5.5 Within thirty (30) days after the termination of this Agreement, the Investigator shall deliver to Sponsor completed CRF pages on RDC.

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the **"Indemnities"**) and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or willful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;

6.1.2 Arising out of errors or omissions by Institution;

6.1.3 arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study; or

6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.

6.2 The Investigator agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the **"indemnities"**)and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an indemnity for harm:

6.2.1 arising out of or relating to the negligence or willful misconduct or malpractices of the Investigator, his study team member/employee or any person for whom the Investigator is responsible at law in performing their obligations under this Agreement;

6.2.2 arising out of or relating to the failure of the Investigator, his or her study team members or employees and any person for whom the Investigator is responsible at lawto comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study ;

6.2.3 arising from a violation of applicable laws and regulations related to the conduct of the Clinical Trial by the Investigator, his or her study team members/ employees or any person for whom the Investigator is responsible at law; or

6.2.4 arising out of from or by reason of any breach or non-frivolous of alleged breach of representation, warranty or covenant herein.

6.3 To the maximum extent permitted by applicable laws, SPONSOR agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting

out of (i) the breach of any of Sponsor representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the IP used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.4 Each Party shall use reasonable efforts to inform the other Parties promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Parties reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 5. The Parties further agree that they have a right to retain their own counsel to conduct a full defense of any such claim or proceeding.

6.5 The Institution, Investigator and Sponsor shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.

6.6 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party(s). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY.

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), Investigator Brochure, informed consent form, subject diaries, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of Sponsor or Sponsor's Affiliates that are: (1) provided to Institution or Investigator in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

7.1 Sponsor Confidential Information and all tangible expressions, in any media, of Sponsor Confidential Information are the sole property of Sponsor. Each party shall endeavor to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution and Investigator agree to treat Sponsor's Confidential Information as it would its own proprietary and confidential information. Institution and Investigator will only accept information from Sponsor which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose Sponsor Confidential Information to any third party. Institution and Investigator agrees not to disclose Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Investigator shall safeguard Sponsor

Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. PUBLICATION

8.1 Institution and/or Investigator shall have the right to publish his own site patients' data generated during the Study. Upon receipt of written instruction from Sponsor, Institution and/or Investigator shall have the right to publish the results of the Study subject to the terms and conditions of this Section 8. Prior to submission for Publication purpose, the Institution and/or Investigator shall provide Sponsor thirty (30) days to review a Publication. If Sponsor requests in writing, the Institution and/or the Investigator shall withhold any publication or presentation an additional sixty (60) days solely to permit Sponsor to seek patent protection and to remove any Confidential Information from all publications. For the purpose of this Section, "Publication" means a paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other disclosure of Study Results, in printed, electronic, oral or other form.

8.2 Inclusion of the Institution and/or Investigator in the authorship of any multi-center publication will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any Publication derived from the Study. The Institution and the Investigator agree that if a Study is part of a multi-center study, any Publication by the Institution and/or Investigator of the results of the Study conducted at Institution shall not be made before the first multi-center publication. In the event there is no multi-center publication within twelve (12) months after a Study has been completed or terminated at all Study sites, and all data has been received, Institution shall have the right to publish its results from the Study, subject to the notice requirements described above.

8.3 Any publication or disclosure by the Investigator contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio.It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7) & (8), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor.

9.2 All Intellectual Property Rights owned by or licensed to the Institution or the Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Investigator, as applicable.

9.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial, the Investigational drug or the Protocol (the **"Clinical Trial Intellectual Property"**) shall be the exclusive property of Sponsor and for this purpose, the Institution and the Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis. The Institution and the Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

9.4 The Institution and the Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential information.

10. MISCELLANEOUS

10 .1 All notices required to be given by one Party to the other shall be deemed to have been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.

10 .2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

10 .3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

10 .4 The Institution and Investigator will be responsible for payment to its employees, study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the study team members or employees or agents may be entitled to receive for performing services. Investigator will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions ,benefits, dues etc. that may be payable to its employees and/or agents.

10.5 This Agreement constitutes the entire Agreement between the Parties and supersedes all prior oral and written understandings between the Parties on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is

incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties.

10.6 The Parties hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.

10.7 Neither the Investigator nor the Institution may assign this Agreement without the prior written consent of Sponsor. Sponsor may assign any or all of its rights and obligations under this Agreement at any time, provided that Sponsor ensures the assignee is bound by the terms hereof.

10.8 The Investigator and the Institution shall not subcontract the whole or any part of the performance of the clinical Study without the prior written consent of Sponsor.This Agreement ensures to the benefit of and binds the Parties and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.

10.9 This Agreement and the obligations of the Parties shall be governed by and construed in accordance with the laws of India .The Parties agree to submit to the exclusive jurisdiction of courts at Mumbai in connection with this Agreement.

10.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach.The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

10.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

11. INTERPRETATION

11.1 Unless the context requires otherwise:

11.1.1. references to this Agreement are to this Agreement as it is from time to time amended;

11.1.2. headings are for convenience only and shall not affect interpretation;

11.1.3. references to the singular include the plural and vice versa, and references to one gender include all genders;

11.1.4. any phrase introduced by the expressions "**including**", "**include**"or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

11.1.5. reference to any law: shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

11.1.6. references to "**writing**" or "**written**" include any modes of reproducing words in a legible and non transitory form but do not include writing on the screen of a visual display unit or other similar device;

11.1.7. references to a numbered clause are references to the clause of or to this Agreement so numbered.

11.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

- ***Signature page follows-***

BY SPONSOR:

Sun Pharma Advanced Research Company Ltd.

Signature: Ajay Singh Solanki

Name:Mr. Ajay Singh Solanki

Designation: GM, Clinical Operations

(who by his signature hereto warrants his authority)

Date: 11. Aug. 2016

Place: Mumbai.

BY INSTITUTION:

Mahatma Gandhi Mission's Medical College & Hospital

Signature:

Name: Dr A G Shroff

Designation: Dean

(who by his/her signature hereto warrants his/her authority)

Date: 17 Aug 2016

Place: Aurangabad

MGM'S Medical College Aurangabad

BY INVESTIGATOR

Signature:

Name: Dr. Chandrashekhar Tamane

Designation: Principal Investigator

(who by his signature here to warrants his authority)

Date: 16 Aug 2016

Place: Aurangabad

APPROVED BY LEC
No.: R17.09.08.16
INITIALS

EXHIBIT-A

Financial Grant

Protocol No.: CLR_16_13

Protocol Title: "A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer."

Investigator's Name: Dr. Chandrashekhar Tamane

Institute Name: Mahatma Gandhi Mission's Medical College & Hospital

Heads	**Amount in INR with breakup**		**Schedule**
Study Start Up Fees	25000		At SIV
Screen failure cost up to 5 subjects	8000/subject		Monthly
Investigator fee per completed subjects	Screening Visit	9000	Monthly
	Cycle 1 Day1	21000	
	Cycle 1 Day 8	5000	
	Cycle 1 Day 15	5000	
	Cycle 2 Day 1	21000	
	Cycle 2 Day 8	5000	
	Cycle 2 Day 15	5000	
	End of study visit	90000	
	Total	**80000**	
Study coordinator salary/month (From Site Initiation Visit to Site Close-out Visit)	12000		Monthly
Phlebotomist charges/ completed subject	Cycle 1	1500	Monthly
	Cycle 2	1500	
	Total	**3000**	
IP reconstitute or charges per reconstitute	500		Monthly
Subject travel reimbursement/visit	1000		Monthly
Subject study participation in period 1 and period 2 *	Cycle 1	2500	Monthly
	Cycle 2	2500	
	Total	**5000**	
Administrative cost/month (Internet, courier, stationary etc)	2500		Monthly
Ethics committee charges	As per actual		Monthly
Hospitalization charges for cycle 1 and cycle 2	As per actual		Monthly
SAE management	As per actual		Monthly
Local lab charges	As per actual		Monthly
Institutional overheads charges	20 % of budget		Monthly
Service tax	15 %		Monthly

1) All invoices will be addressed to: Mr. Ashok Gupta, Sun Pharma Advanced Research Company Ltd., Clinical Research Dept, 17/B,Mahal industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai 400093, Maharashtra, India.
2) *As per Indian Council for Medical Research guidelines 2006 on "Ethical Guidelines for Biomedical Research on Human Participants"

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL73206550360108P
Certificate Issued Date	:	20-Apr-2017 05:53 PM
Account Reference	:	IMPACC (IV)/ dl719703/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL71970347025481731176P
Purchased by	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Second Party	:	MGMMC AND HOSPITAL AURANGABAD
Stamp Duty Paid By	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 05 MAY 2017

JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
(AS THE CRO)
AND
DR. ASHISH RAMCHANDRARAO DESHMUKH
(AS THE PRINCIPAL INVESTIGATOR)
AND
MAHATMA GANDHI MISSION'S MEDICAL COLLEGE AND HOSPITAl
(AS THE SITE/INSTITUTION)

CLINICAL TRIAL AGREEMENT

TABLE OF CONTENTS

ARD

This Clinical Trial Agreement (the "**Agreement**") is dated: **05 May 2017.**

BETWEEN:

1. **JSS Medical Research India Private Limited.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Dr. Renu Razdan, Vice President, India being authorized to sign this Agreement on behalf of Sponsor, Veloce BioPharma LLC (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

2. **Dr Ashish Ramchandrarao Deshmukh** , working as Professor & Head at Skin & VD Department, Mahatma Gandhi Mission's Medical College and Hospital having his residence at Aurangabad (hereinafter referred to as the "PI" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

3. **Mahatma Gandhi Mission's Medical College and Hospital**, a hospital/health care registered under the provisions of [Indian Companies Act, 1956 OR any other relevant law], having its registered office at N-6,Cidco, Aurangabd-431003. Maharashtra. acting through its Dr Rajendra Bohra being authorized to sign this Agreement (hereinafter referred to as the "Site" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.

B. The Site is engaged in Health care and the PI is an Employee [employee/consultant] at the Site.

C. Veloce BioPharma LLC is the Sponsor, desires to conduct a clinical trial in respect of the **Topical Povidone-Iodine (PVP-I, 2% [W/W]) in Pediatric Subjects for the Treatment of Molluscum Contagiosum**, and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

D. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

ARD

1. **Definitions and Interpretations**

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, by law, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by the Sponsor.

"**Clinical Trial**" shall mean a clinical trial conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"Dispute Notice" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by the Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and well being of all such actual and potential research participants.

"**Feasibility Study**" shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

ARD

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**Indian GCP**" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. "**Information Brochure**" shall mean the information brochure of the Sponsor.

"**Informed Consent Form**" or "**ICF**" shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject .

"**Investigational Products**" shall mean the chemical compound invented by the Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by the Sponsor.

"**Invoice**" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"**Subject**" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"**Payment Milestone**" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"**Protocol**" shall mean Protocol No. VBP-245-MCV as provided by the Sponsor.

"**Price**" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'C' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"**Screen Failure**" shall mean the screen failure as defined in the Protocol.

"**Serious Adverse Event**" or an "**SAE**" includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

ARD

"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

1.2.2 references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

1.2.3 references to this Agreement include the Recitals and the Schedules;

1.2.4 the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

1.2.5 references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

1.2.6 references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

1.2.7 references to any Party include its successors, transferees and permitted assignees.

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the JSS India/Veloce BioPharma in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

ARD

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of veloce BioPharma.
ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Study Report preparation & IMP logistic management

5.2 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible that the Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.

b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or Veloce BioPharma in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or the Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or the Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

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6 **Representations, Warranties and Covenants.**

6.1 JSS India represents, warrants and covenants to the Sponsor as follows:

(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause the Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the JSS India/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or

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misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7 Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or the Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

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8 Ownership of Property and Data

Veloce BioPharma LLC shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of this Agreement.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: **(a)** the date on which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) **(b)** the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India / Veloce may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/Veloce so elect, comprise: (a) inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

JSS India and the Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to the Sponsor and JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

11.1 Budget: The CRO, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the written consent of JSS India before administration of such tests or services.

11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number

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of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

(b) the JSS India, if so authorized, shall pay the invoiced amount within forty five (45) business days of the date of the original invoice received at JSS. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The Total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	MGM MEDICAL COLLEGE
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAATM4256E
ACCOUNT NUMBER AND BANK DETAILS	0376104000000107 IDBI Bank, Aurangabad IFSC Cod:- IBKL0000376 MICR CODE:- 431259008 Bank AD Code:- 6910452-6240008 Swift Code:- IBKLINBBABD

11.2.2 Taxes: Any service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or the Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

a. JSS India shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering JSS India, the PI and the Site, (iii) human clinical trial insurance covering JSS India, the PI and the Site during the Term.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of the Veloce BioPharma LLC. shall indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys'

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fees and expenses of litigation) ("**Loss**") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and JSS India or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 3 above, directly or due to a third party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 3 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defences. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 3 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of the Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if the Sponsor fails to initiate the same within fifteen (15)

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business days of receipt of the notice in writing of such legal claim or proceeding from the Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

13.4.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

13.6 The CRO shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 Confidentiality

a. All of the information disclosed by JSS India or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor

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associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

15.2 The CRO may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.

15.3 In the event that JSS India exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

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15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India:

JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,
Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India

Attention: Dr. Renu Razdan
Designation: Vice President, India Operations
Telephone: +91 129 6613 500

E-mail: renu.razdan@jssresearch.com

If to the PI:

Dr Ashish Deshmukh
Skin & VD Department, Mahatma Gandhi Mission's Medical College & Hospital,
N-6 CIDCO, Aurangabad – 431003.
Maharashtra.

If to the Site:

Clinical Research Department, Opposite Blood Bank,
Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO,
Aurangabad – 431003. Maharashtra.

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by the Sponsor, DCGI and Institutional Ethic Committee.

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16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.

16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and the Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be New Delhi, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of

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the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India

By: _____
Print Name: Dr. Renu Razdan

Title: Vice President, India- Operations
JSS Medical Research India Private Limited

Date: May 8, 2017

The Principal Investigator

By: _____
Print Name: Dr Ashish Ramchandrarao Deshmukh

Title: Professor & Head, Skin & VD Department
Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad – 431003. Maharashtra.

Date: 30 May 2017

The Site

By: _____
Print Name: Dr Rajendra Bohra

Title: Dean
Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad – 431003. Maharashtra.

Date: 02 JUNE 2017

Dr. A. R. Deshmukh
M.D. D.N.B.
Professor
Dept.
MGM Medical Co... ...n,A'bad.
Reg.

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Schedule A

[List of services to be provided by the PI and/or the Site]

Protocol Title: A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Phase II Study to Evaluate the Efficacy, Tolerability, and Safety of Topical Povidone-Iodine (PVP-I, 2% [W/W]) in Pediatric Subjects for the Treatment of Molluscum Contagiosum
Protocol ID: VBP-245-MCV

List of services to be provided by the PI and/or the Site, but not limited to:

1. Identification of protocol eligible patients for the study
2. Administration of informed consent process and AV recording
3. Recruiting patients as per protocol inclusion & exclusion criteria
4. Treat study participants as per randomization & adequate follow-up
5. Taking complete medical history of the patients
6. Responsibility for adverse events reporting
7. Writing the patient study summary-completion of source documentation
8. Compliance to study subject visits as per Protocol
9. Transcription of data in to electronic case report form & resolution of data queries
10. Allow oversee of the study by CRO or their designee through regular monitoring visits
11. Site readiness for regulatory inspection & external/internal audits
12. IP management as per protocol and Archival of study documents & material
13. Regulatory document submission & management
14. Maintain Study site files

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Schedule B
Budget and Payment Schedules

Payment shall be made against invoices sent every month according to table mentioned below.

The Parties understand and agree that the currency of the Agreement is and shall remain India Rupee (INR) and shall not be modified notwithstanding any exchange fluctuations that may occur.

All invoices shall be sent to the following address:

JSS Medical Research India Private Limited.
Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Near Sarai Khwaja Metro Station,
Sector-27D, Faridabad – 121003 (INDIA)

Each invoice must be an original copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

a) The Research Institution's Name and Address as it is written at the front of this Agreement
b) A description of the deliverable (e.g. final written report) associated with the invoice
c) The total invoice amount in the currency specified in this Agreement, Payee Name, PAN
d) Signed & date by authorized signatory

Payment Schedule/Milestones per patient:

Visit Type	Amount INR	Approx. Percentage
Visit 1 (Screening/Baseline/Randomization)	5200	25%
Visit 2 (Day 14)	5200	25%
Visit 3 (Day 35)	5200	25%
Visit 4 (Day 60/ Study completion)	5200	25%
Total for per protocol completed patient	20,800	100%
		--
Institutional Overhead; 30% of the budget	6240	--
Miscellaneous (Stationaries etc.)	1000	--
Total budget per Patient	28040	--

The cost for the trial will be as mentioned below:

a) The cost per protocol-correct and completed subject will be INR 28,040 . (including Institutional overhead)
Note: Completed patient means once the subject has completed the final follow up and complete data entered and verified in the eCRF by the monitor.

This will include the following fees, as applicable, but not limiting to:

- The PI fees, study team fees, costs for unscheduled visits, site infrastructure maintenance for this study, stationary, courier and other study-related bills.

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b) If required/requested by site, A refundable advance amount of INR 20,000 would be issued to the site upon receipt of completely executed agreement and unconditional EC approval. This amount will be adjusted from the cost of the 1st subject randomized & completed per protocol.

c) The following costs incurred by site, where applicable, would be reimbursed to site upon receipt by CRO of original receipts/ bills:

i. Fees related to local Ethics Committee reviews
ii. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
iii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses in connection with this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imbursement will be paid on actual up to Rs. 500 per visit upon producing the vouchers/ bills for the same to CRO.

d) The fees for a screen failure patient will be INR 2500 /-. This screen failure payment includes all charges.

e) For the Unscheduled visit, travel reimbursement will be paid on actual upto INR 500 per visit upon receipt of bill (upto 2 unscheduled visits during the study period).

e) Institutional overhead 30 % of the total budget.
f) Archival fee as applicable at the study close out INR 75000/- (5000 / Year).

ARD

SCHEDULE C

JSS India on behalf of Veloce will make the payments as follows:

(i) Payments will be made once the CRFs for the patient visits have been verified by the CRO/ designee & query has been resolved. Invoices will be raised on monthly basis and sent to CRO for payment. Invoices will be raised on the basis work completed during previous month In the event that a subject withdraws or is withdrawn from the Trial for reasons beyond the Investigator's control (but after commencing the dosing regimen in accordance with the Protocol), payment shall be made pro rata (based on the number of visits completed) in respect of that subject provided all data in respect of that subject up to the time of that subject's withdrawal from the Trial have been completed and sent to and accepted by CRO.

(ii) Invoices will be paid within 45 business days of receipts to the payee. Service tax as applicable will be levied on each invoices according to the guidelines of service tax rules of India.

(iii) From each invoice CRO will keep last one completed subjects payment as retention money and the same will be paid once all queries are resolved and Clinical trial/Site is closed out in all respects.

(iv) There is no other amount payable to Institute/Investigator for the Clinical Trial (except) mentioned in this agreement.

(v) The above given budget* is for 1 subject. If number of subjects is randomised more or less, actual invoices will vary in proportion to the work done i.e. visits completed. The agreement will be applicable again subject to recruitment of the Patients.

(vi) Above budget* does not include any Related Adverse Event or Serious Adverse Event expenses. Any related Adverse Event or Serious Adverse Event expenses will be reimbursed on actual. Reimbursement of Adverse Event or Serious Adverse Event management will include but not limited to Investigations, Hospitalisation, Treatment costs. Site agrees to take approval for any special investigations in case of Adverse Events. Site agrees to give timely update on the plan of management in terms of cost, on the cost incurred in management of the above events.

vii) In case of early termination of Clinical Trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee will refund the extra money. In case there is any amount payable to payee the same will be paid by CRO.

viii) All payments are subject to TDS (other taxes as applicable) except Travel reimbursements of patients and all payments will be made once payment is received by CRO from Sponsor.

ARD

Summary of the items included in payment & items not to be reimbursed:

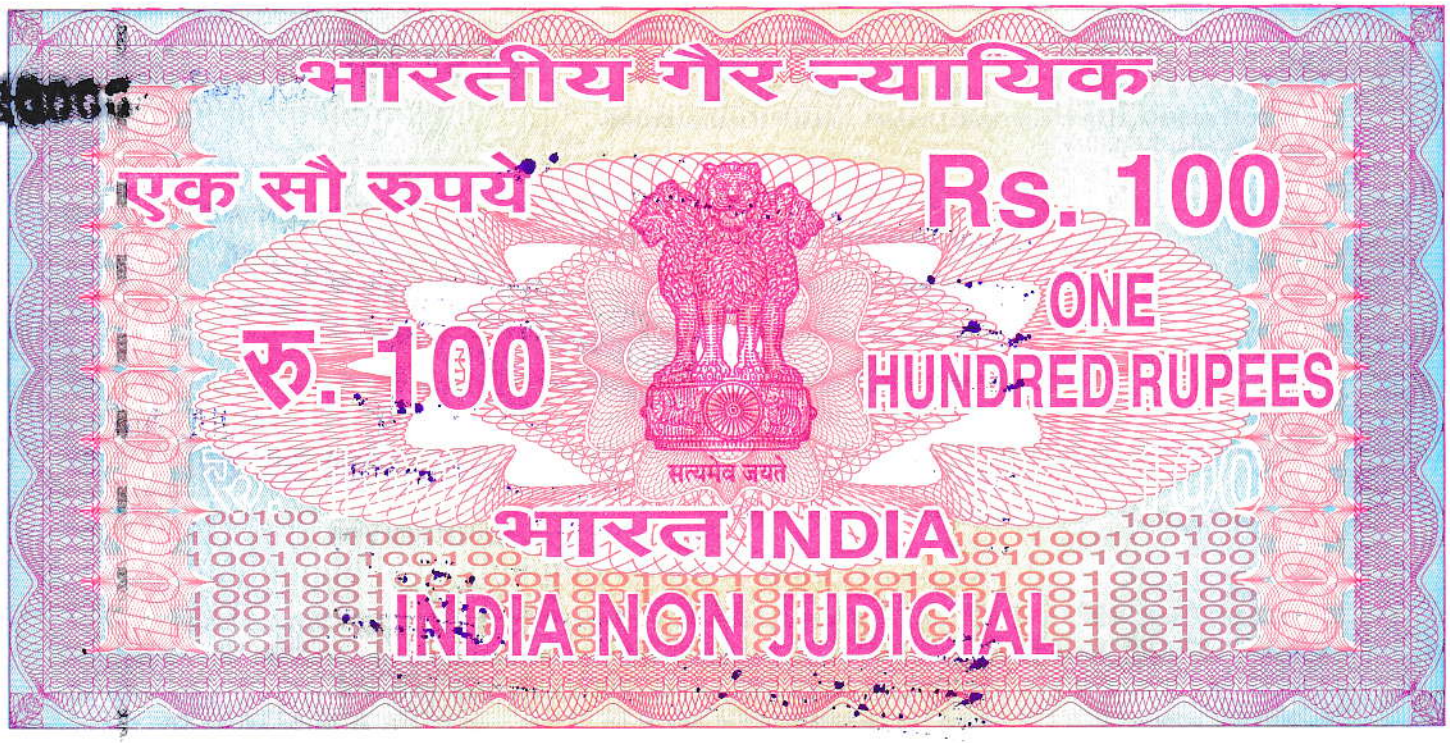
Items included in payment:

Items included in Professional fees of per patient cost:
• PI fees
• Clinical Trial team fees
• Administrative cost
• Payments for unscheduled visits
• Site infrastructure (including Telephone/ fax/ internet), IMP storage.
• Stationary and Couriers
Pass through costs to be paid on Actuals:
• Ethics Committee fees
• SAE management costs, if any
• Subject Compensation if any
• Travel reimbursements of patients
• Archival Fees

Items not to be reimbursed, but not limited to:

Buying new equipment
Maintenance of equipment
Salary for study staff

ARD



महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ SE 665317

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.कि.क. / 000095
- 4 JUL 2017
सक्षम अधिकारी

श्री. प्र. ना. चिंचघरे

CLINICAL TRIAL AGREEMENT

This **CLINICAL TRIAL AGREEMENT** (the "Agreement") is effective as of the date of last signature (the "Effective Date"), by and among;

Mahatma Gandhi Mission's Medical College and Hospital located at N-6, Cidco, Aurangabad-431003, Maharashtra, India (the "Institution"),

-and-

Dr. Deepak Bhosle, an employee of the Institution, acting within the scope of his/her employment, located at N-6, Cidco, Aurangabad-431003, Maharashtra, India, who shall serve as the principal investigator ("Investigator") for the Study as defined below. The Institution and the Investigator may be collectively referred to as the "Site".

11 JUL 2017

जोडपत्र - १ Annexure - I

फक्त प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव _____

मुद्रांक विकत घेणाऱ्याचे रहिवाशी पत्ता _____

मुद्रांक विक्रीबाबतची नोंद वही अनु. क्रमांक _____ दिनांक _____

PHARMACEUTICAL RESEARCH ASSOCIATES INDIA PVT. LTD.
The Qube, A-609, C.T.S. No. 1498 A/2, M. V. Road, Marol, Andheri (East),
Mumbai - 400 059. India

मुद्रांक विकत घेणाऱ्याची सही

परवानाधारक मुद्रांक विक्रेत्याची सही 11 JUL 2017

परवाना क्रमांक : ८०००१५

मुद्रांक विक्रीचे ठिकाण/पत्ता : अंधेरी कोर्ट आर अशोसिएशन

एन. एल. कोर्ट, अंधेरी रेल्वे स्टेशनच्या बाजुला,

अंधेरी (पूर्व), मुंबई - ४०० ०६९.

शासकीय कार्यालयाकरिता /कोर्टासाठी सादर करण्यासाठी मुद्रांक कागदाची आवश्यकता नाही. (शासन अधि. क्र. मि. ०१/०९/२००४ दुरुस्ती)

टीप: ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

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-and-

Grapecity Research Solutions LLP, Site Management Organization located at D/2, Prakash Hsg Society, Thergaon, Near Kalewadi Fata, Pune- 411033, Maharashtra, India, shall serve as the site management organization (the "SMO") who will provide the Institution and the Investigator certain clinical trial related services *in relation to the study as defined below.*

-and-

Pharmaceutical Research Associates India Private Limited located at The Qube, A-602 and A-603, C.T.S. No. 1498 A/2, M.V. Road, Marol, Andheri (East), Mumbai - 400 059, India ("PRA").

ASTRAZENECA AB located at 151 85 Södertälje, Sweden (the "Sponsor") will assume the role of sponsor with respect to the Study identified below and has retained PRA (under a separate written agreement) to serve as the Sponsor's contract research organization to manage the Study on its behalf.

1. STATEMENT OF WORK.

(a) The Investigator will conduct the clinical research study entitled "***A 26 Week, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase 3 Trial with a 26 Week Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Pediatric Patients with Type 2 Diabetes Mellitus who are between 10 and below 18 years of age***" (the "Study"), bearing protocol number D1680C00019, as may be amended from time to time (the "Protocol"), the provisions of which are incorporated herein by reference. The Investigator shall perform the Study in conformance with: (i) generally accepted standards of good clinical practice, (ii) an ethical manner and in a manner that appropriately protects the safety, security, and well-being of the Study subjects and any data arising from the Study (iii) the Protocol, (iv) the FDA Form 1572, and (v) all applicable laws, rules and regulations governing the conduct of the Study and the activities or interactions under this Agreement, including, but not limited to the Indian Drugs and Cosmetics Act, 1940, the Indian Drugs and Cosmetics Rules, 1945, and any other guidelines and notifications issues by the Central Drug Standard Control Organisation (as may be amended from time to time) and DCGI Guidelines on Audio Visual Recording of Informed Consent, as applicable to the conduct of the Study. The Institution shall not reassign the conduct of the Study to another investigator without Sponsor's express written consent. If the Investigator is unable to perform the duties required by this Agreement, the Institution shall promptly notify PRA and the Sponsor in writing. If a mutually acceptable replacement is not available, this Agreement may be terminated as provided herein.

(b) The Institution and SMO shall provide appropriate resources and facilities so the Investigator can conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Site and SMO shall ensure that only individuals who are appropriately trained and qualified will assist in conducting the Study. The Site and SMO are responsible for ensuring that all personnel participating in the Study ("Study Team") comply with the terms of this Agreement, excluding personnel supplied by PRA or Sponsor. Institution, Investigator and SMO agree to promptly notify PRA and the Sponsor in the event any Study Team member is reported to or comes under investigation by any regulatory authority, licensing board, independent ethics committee or institutional review board, and further agrees to promptly discontinue the use of any such personnel in connection with the

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Study unless the Sponsor consents in writing to the continued use of such personnel. Unless otherwise agreed to in writing by the parties, the Site and SMO shall conduct the Study only at the facilities indicated in this Agreement.

(c) Investigator and/or Study Team may be invited to attend and participate in meetings relating to the Study. The parties agree that there will be no additional compensation for attendance or participation at such meetings by the Investigator or any Study Team. If the Investigator and/or Study Team are required to perform any additional tasks, over and above those required for the conduct of the Study, the terms and obligations for the provision of such services shall be subject to a separate agreement.

2. PAYMENT.

(a) PRA will pay the SMO according to the Payment Terms attached hereto as Exhibit A ("Payment Terms") and the Budget attached hereto as Exhibit B ("Budget"), upon receipt of invoices and other appropriate documentation as specified therein. Payments due hereunder are pass-through payments from Sponsor that will be sent after such payments are received by PRA from Sponsor. PRA shall exercise reasonable efforts to ensure timely receipt of pass-through payments from Sponsor.

(b) The Institution and the Investigator appoints the SMO as their duly designated payee, authorized to receive Study payment of their behalf ("Payee"). The Payee shall provide full payment instructions and bank details, in writing to PRA in the Payment Information Checklist ("PIC"), before any payment can be made. The Payee is obliged to inform PRA, in writing, of any changes or required updates of payment instructions and/or bank details. The parties agree that any change of or update to the Payee's bank details contained in the PIC may be effected through a written notice and shall not of itself require a formal Amendment to this Agreement. The Institution, Investigator and SMO agree and acknowledge that any payment made by the Sponsor or PRA to the Payee shall be deemed payment to the Institution and/or the Investigator and/or SMO and the Institution, Investigator and SMO shall have no recourse from PRA or Sponsor.

(c) The Site is an independent contractor, and the SMO shall be deemed an agent of the Site and neither PRA nor Sponsor is responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site, SMO or any of their personnel.

(d) The Investigator and any sub-investigators will complete and sign a financial disclosure form when reasonably requested to do so by PRA or Sponsor. These forms shall be promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion.

(e) The Site and SMO hereby agree that no third party will be charged for any aspect of treatment or subject care for which the Payee has invoiced or been paid under this Agreement. The Institution hereby agrees that neither participants in the Study nor any third party will be charged for **Saxagliptin, Dapagliflozin and placebo** (the "Study Drug") or any comparator drugs provided for this Study, nor shall Payee include such cost in any cost report to third-party payers.

(f) Unless otherwise agreed herein, payments will be made for evaluable subjects and for eligible subjects only. An eligible subject is one who meets all of the inclusion requirements and does not meet any of the exclusion criteria of the Protocol, who was enrolled by Investigator, and from whom informed

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consent has been obtained. An evaluable subject is one for whom case report forms ("CRFs") have been properly completed in accordance with the Protocol, and who has completed the appropriate Study procedures as set forth in the Protocol, and undergone the evaluations required by the Protocol.

(g) The parties acknowledge and agree that the compensation provided for Site's performance under the Agreement represents the fair market value for the services conducted by Site and has been agreed independently from any business the Institution or the Investigator has made or may make in relation to the ordering of products or services of the Sponsor.

3. RECORDKEEPING; REPORTING; ACCESS.

(a) Authorized representatives of Sponsor and/or PRA have the right, upon reasonable advance notice, and during regular business hours, to: (i) audit and examine the Site's facilities required for performance of the Study; and (ii) review all data, records and work products relating to the Study, and if necessary, make copies of such data, records and work products, provided such copies do not include any unauthorized individually-identifiable information of a Study subject. The Site shall maintain complete and accurate records related to the Study, and shall retain all such records resulting from the Study for fifteen (15) years or later if required under applicable laws and regulations.

(b) The Investigator will deliver CRFs to PRA within fourteen (14) days of Investigator's review or in accordance with PRA's reasonable written instructions, as the case may be. The Investigator shall be available at reasonable times during normal business hours to meet with Study monitors and answer questions regarding the conduct of the Study. If PRA must use or access the Site's computer systems, it will do so in accordance with the Site's instructions and will only use acquired information for the purpose of the Study and in accordance with applicable laws.

(c) The Site and SMO will promptly notify Sponsor and PRA if any regulatory authority notifies the Institution or Investigator of a pending inspection or makes any written or oral enquiries relating to the Study, and will promptly forward to Sponsor and PRA copies of any written communication received as a result of such inspection or enquiry which are related to the Study. The Site and SMO shall also provide to Sponsor and PRA copies of any documents provided to any inspector that relate to the Study.

4. CONFIDENTIALITY.

The Protocol, Study Drug(s) (including Study Documentation and Intellectual Property (as defined in Clause 7), CRFs, and any and all information, data, reports or documents, disclosed to or generated by the Site or any Study Team members regarding the work performed under this Agreement (other than subject medical records) or which otherwise relates to this Study ("Confidential Information") belong to Sponsor in accordance with clause 7 below and shall not be disclosed by the Site or SMO to any third party or be used for any purpose other than the performance of the Study without the prior written consent of Sponsor, during a period of ten (10) years after the termination of the performance of the Agreement. The above obligations of confidentiality shall not apply to the extent Confidential Information:

(a) is or becomes, through no fault of the Site or SMO, part of the public knowledge;

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(b) the Site or SMO can demonstrate was already lawfully in the Site or SMO's possession on the date of disclosure to the Site or SMO and not subject to prior confidentiality obligations;

(c) is acquired by the Site or SMO from any third party without restrictions on disclosure; or

(d) is developed by the Site or SMO independently, without the use or benefit of Confidential Information, and as evidenced by competent written records.

Permitted Disclosures. The Site and SMO's obligations of non-disclosure and non-use of Confidential Information shall not apply to the extent the Site and SMO are required by law to disclose Confidential Information, provided the Site or SMO promptly notifies Sponsor of such a requirement prior to disclosure to allow Sponsor the reasonable opportunity to oppose the requirement or seek an appropriate protective order. This Section 4 does not limit the Site and SMO's rights or obligations under Section 6 Publication.

5. PRIVACY AND DATA PROTECTION.

The parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institution, SMO and Investigator will obtain the consent of each Data Subject, and the Investigator will provide his/her consent and will obtain the Study Team members' consent with regard to their own personal data, to the use, processing, holding and transfer of their data to countries other than their own, that may not have the same level of data protection as their own country. . The Investigator and the Study Team have the right to access and correct their personal data. In order to exercise this right, the requests should be addressed to the Sponsor and PRA.

6. PUBLICATION.

(a) SMO shall have no publication rights over the Study. The Institution and the Investigator shall be entitled to publish the results of, or make presentations related to, the Study, provided that any publications or presentations to be made within 2 years of completion of the Study shall require the Sponsor's prior written consent. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors guidelines, (ii) not be false or misleading, (iii) comply with all applicable laws, (iv) not be made for any commercial purpose.

(b) The Institution and/or the Investigator shall provide the Sponsor with copies of any materials relating to the Study, or the Developed Technology (defined in clause 7 below) that either intends to publish (or submit for publication) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.

(c) At the request of the Sponsor and/or PRA, the Institution and/or the Investigator:

(i) shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and

(ii) shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Sponsor receives the material to allow the Sponsor to

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take such measures as the Sponsor considers necessary to preserve its proprietary rights and/or protect its Confidential Information.

(iii) The Institution and the Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or Developed Technology, as well as in any financial disclosure information relating to the Study: "AstraZeneca sponsored this clinical trial."

(iv) The Sponsor has a long-standing commitment to transparency, and the Institution and the Investigator acknowledge that the Sponsor shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format (including www.astrazenecaclinicaltrials.com), and/or provide such results to the regulatory authorities.

(v) If the Sponsor invites the Investigator to be an author of a Sponsor-managed publication, the Investigator shall direct, draft and/or review the proposed publication, and approve the final version of the publication to be published. No compensation shall be provided in respect of any such authorship. Any authorship, medical writing, editorial or logistical support provided to the Investigator or the Institution by the Sponsor in respect of publication shall be subject to the Sponsor's publications policy, details of which are available at www.astrazeneca.com.

7. INTELLECTUAL PROPERTY RIGHTS.

(a) Except as expressly set out in this Agreement, no party nor the Sponsor shall acquire any right, title or interest in or to the Intellectual Property of any of the other parties or the Sponsor or their licensors.

(b) The Sponsor shall own all rights and title in any Intellectual Property arising from the Study or relating to the Study Drug, any Developed Technology and the Study Documentation, except to the extent that the Institution and Investigator are required to retain any Study Documentation in accordance with the International Conference on Harmonisation Guideline for good clinical practice (including any modification or re-enactment thereto) and the applicable laws and regulations. The Institution, the Investigator and/or SMO shall promptly disclose any such Intellectual Property to the Sponsor and PRA in writing or in such other format as the parties may agree.

(c) To the extent capable of prospective assignment, the Institution, Investigator and SMO hereby assign to the Sponsor (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 7(b) above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution, Investigator and/or SMO shall assign, and shall procure that the Study Team shall assign, such Intellectual Property to the Sponsor (or its Designee) on creation.

(d) The Institution, Investigator and/or SMO shall, and shall ensure that the Study Team take all steps as the Sponsor and/or PRA may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 7.

(e) The Sponsor grants to the Institution a perpetual, royalty-free non-exclusive licence to use the Intellectual Property arising only from the Study for internal research and educational purposes only, and with no right to grant sub-licences. The SMO shall have no such rights. The provisions of Clauses

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4 and 6 of this Agreement shall continue to apply in relation to any such licence.

(f) The capitalised terms set out below that are referred to in this Clause or other parts of this Agreement shall have the following meanings:

(1) "**Designee**" means any person designated by the Sponsor in writing who undertakes activities on behalf of the Sponsor in relation to the Study, which may include an affiliate or PRA.

(2) "**Developed Technology**" means any inventions, discoveries, improvements or developments made by the Institution, the Investigator or any Study Team (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to the Study Drug, or the use thereof.

(3) "**Intellectual Property**" means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

(4) "**Study Documentation**" means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study and/or Study Drug, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

8. MATERIAL TRANSFER; RETURN OF MATERIALS; EQUIPMENT.

(a) During the Study, Sponsor or Sponsor's designee shall provide to the Site, at Sponsor's expense, the Study Drug, placebo and other compounds, or agents for the performance of the Study (collectively, the "Materials"). The Materials will be used only by the Site for performance of the Study in accordance with the Protocol and this Agreement. The Site shall handle, store, and ship or dispose of Materials in accordance with the Protocol and any reasonable written instructions provided by Sponsor (or Sponsor's designee), and in compliance with all applicable, local and national laws, rules and regulations including, but not limited to, those governing hazardous substances.

(b) Unless otherwise agreed by the parties, in the event that the Protocol for a Study requires the collection of blood, tissue or other biological materials from subjects ("Biological Materials") the site and SMO agree that the use of such Biological Materials shall be limited to those tests, analyses or procedures identified in the Protocol and informed consent as approved by the IRB/EC.

(c) Upon completion or termination of the Study, all Materials furnished to the Site by Sponsor or Sponsor's designee shall be promptly returned or destroyed as directed by PRA. Shipping costs relating thereto will be paid by PRA.

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(d) If Sponsor provides equipment to the Site, such equipment shall be used only by the Site for the performance of the Study and in accordance with any written instructions of use provided by the equipment manufacturer or Sponsor. Such equipment is property of the Sponsor or Sponsor's designee and shall be returned, at Sponsor's expense, to Sponsor (or Sponsor's designee), upon Sponsor's written request or upon completion of the Study. The equipment to be provided is listed at Exhibit C. Site will use reasonable care to maintain such equipment while in its possession, provided that Sponsor shall be responsible for maintenance and repair costs due to normal wear and tear. If Institution and/or Investigator do not return the equipment, the fair market value of the equipment, as determined by Sponsor or Sponsor's designee, will be deducted from the final payment.

9. TERM; TERMINATION.

(a) This Agreement shall commence on the Effective Date and shall continue in force until the Study has been completed at the Site.

(b) This Agreement may be terminated by the Sponsor or PRA at any time and for any reason upon thirty (30) days written notice, or immediately upon written notice by any party where such party, on reasonable grounds, believes the Study should cease in the interests of health, safety or well-being of Study subjects.

(c) Upon the effective date of termination of this Agreement, an accounting shall be conducted by the Site, subject to verification by PRA. Following PRA's receipt of adequate documentation, PRA will pay for:

(i) all services properly rendered and monies properly expended by the Site, through the effective date of termination which have not yet been paid by PRA; and

(ii) non-cancelable obligations properly incurred for the Study by the Site prior to receipt of notice of termination.

(d) If the Site has been paid any amounts which have not been earned hereunder as of the date of termination, the Institution shall promptly return to PRA all such unearned funds within 30 days.

(e) Immediately upon receipt of a notice of termination, the Investigator shall stop screening and enrolling subjects into the Study and shall, as directed by PRA, cease conducting Study procedures on subjects already enrolled in the Study, to the extent medically permissible, and to cease, to the extent reasonably feasible, from incurring any additional Study expenses.

(f) The SMO shall have no termination rights over this Agreement.

10. INSURANCE.

The parties acknowledge that Sponsor will ensure adequate provision is made by way of insurance or indemnity arrangements sufficient to meet its obligations and liabilities under applicable laws as the sponsor of the Study, in particular towards Study subjects for personal injury arising as a result of

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participation in the Study.

11. STATUS OF SPONSOR.

In order to satisfy pre-existing contractual obligations owed by PRA to the Sponsor, the parties agree that the Sponsor and its affiliates are the intended third-party beneficiaries of the rights under this Agreement, and accordingly has concomitant enforceable rights in relation to this Clause. The parties acknowledge that conferring third-party beneficiary status upon the Sponsor and its affiliates is a direct and material purpose of the parties entering into this Agreement. Rights under this Clause 12 cannot be modified without the Sponsor's consent. To the extent applicable law does not allow vesting of any rights directly in Sponsor under this Agreement, such rights will vest in PRA, on Sponsor's behalf and PRA may grant licenses to the Sponsor to effect such rights.

12. CERTIFICATIONS.

(a) The Institution, Investigator and SMO hereby individually certify that they have not been debarred or disqualified from participating in clinical research under any laws or regulations. If during the term of this Agreement, the Institution, Investigator or SMO (i) becomes debarred or disqualified or (ii) receives notice or threat of an action with respect to its debarment or disqualification, the Institution, Investigator or SMO, as the case may be, shall notify PRA immediately.

(b) The Institution, Investigator and SMO hereby individually certify that they have not and will not use in any capacity the services of any individual or entity which has been debarred or disqualified from participating in clinical research under any laws or regulations. In the event that the Institution, Investigator or SMO becomes aware of the debarment, threatened debarment, disqualification or threatened disqualification of any such individual or entity, the Institution and/or the Investigator and/or SMO, as the case may be, shall notify PRA immediately.

(c) The Institution, Investigator and SMO declare that neither the Investigator nor any member of the Study Team is subject to any conflicting obligations or legal impediments and/or has any financial, contractual or other interests in the outcome of the Study that might interfere with the performance of the Study or that is likely to affect the reliability and robustness of the data generated in the Study. The Investigator shall inform the Sponsor immediately upon learning of the existence of any financial arrangement or interest between the Investigator or member of the Study Team and the Sponsor.

(d) The Institution, Investigator and SMO individually warrant and promise that, in connection with this Agreement, it/he/she has not and will not (directly or indirectly) make any improper payment or offer (or authorizing another to pay or offer) money or anything of value to a government official or any other person connected with the provision of services under this Agreement, in order to improperly influence any act or decision of such official or person, to induce such official or person to do or omit to do any act in violation of his or her relevant duty, to obtain any improper advantage, to procure improper performance of a function or activity associated with this Agreement or in the case of a government official, to induce such official to use his or her influence improperly to affect or influence any act or decision of a government.

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13. ASSIGNABILITY.

Site and SMO may not assign any of its rights or delegate any performance under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner except with the prior written consent of PRA, and any purported assignment or delegation without PRA's written consent is void. Except for the third-party beneficiary rights granted to the Sponsor and its affiliates in this Agreement, any person who is not a party to this Agreement shall not have any rights under it and shall not be able to enforce any term of this Agreement.

14. NOTICES.

With the exception of Study funds paid by PRA pursuant to Section 2 hereof, all notices required or permitted to be given under this Agreement shall be in writing and shall be (a) delivered personally, (b) sent by certified mail, or (c) sent by a nationally-recognised courier guaranteeing next-day delivery, to the recipients below. The parties agree that changes to the addresses below for receipt of notices under this Section may be effected by a letter signed by the relevant party and does not require an amendment to this Agreement signed by all parties:

If to PRA:	**Pharmaceutical Research Associates India Private Limited** The Qube, A-602 and A-603 C.T.S. No. 1498 A/2 M.V. Road, Marol, Andheri (East), Mumbai 400 059 India Attention: Clinical Operations Director
If to the Sponsor:	**AstraZeneca AB** 151 85 Södertälje, Sweden Attention: Legal Department
If to the Institution:	**Mahatma Gandhi Mission's Medical College and Hospital** N-6, Cidco, Aurangabad-431003, Maharashtra, India Attention: Dr. Deepak Bhosle
If to the Investigator:	**Dr. Deepak Bhosle** N-6, Cidco, Aurangabad-431003, Maharashtra, India
If to the SMO:	**Grapecity Research Solutions LLP** D/2, Prakash Hsg Society, Thergaon, Near Kalewadi Fata, Pune- 411033, Maharashtra, India Attention: Dr. Sushil Chaudhary

15. USE OF NAMES.

The Institution, Investigator and SMO shall not use the name, symbols and/or trademarks of PRA or the Sponsor in any form of publicity in connection with the Study unless explicitly approved by PRA or the Sponsor in advance or specifically allowed under the terms of this Agreement. Institution, Investigator and SMO agree that, in accordance with applicable laws, Sponsor may make public the amount of funding

PRAHEALTHSCIENCES

provided hereunder for the conduct of the Study and may identify Institution, Investigator and SMO as part of this disclosure or as part of any Study recruitment activities or other Study-related meetings.

16. WAIVER; SEVERABILITY.

No waiver of any term or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of such term or condition, or of any other term or condition of this Agreement. If any terms or conditions of this Agreement are held to be invalid, illegal or unenforceable the remaining terms and conditions contained herein shall not be affected.

17. ENTIRE AGREEMENT; EXHIBITS; COUNTERPARTS.

This Agreement, including the Exhibits attached hereto, constitutes the full understanding of the parties with respect to the subject matter hereof and a complete and exclusive statement of the terms of their agreement, and no terms, conditions, understanding or agreement purporting to amend, modify, vary or waive the terms of this Agreement shall be binding unless made in writing and signed by an authorised representative of each party hereto. This Agreement and any amendment hereto may be executed in several counterparts, each of which shall be deemed an original but taken together shall constitute one and the same instrument.

18. CONTINUING OBLIGATION; SURVIVAL OF PROVISIONS.

Except as otherwise specifically provided herein, termination of this Agreement shall not relieve any party hereto from any obligation under this Agreement that accrued or arose from facts and circumstances in existence prior thereto. In addition, the provisions of this Agreement that by their nature contemplate continuing obligations shall survive expiration or termination of this Agreement.

19. GOVERNING LAW.

This Agreement shall be governed by the laws of the country where the services are performed excluding conflict of law rules.

SIGNATURES APPEAR ON FOLLOWING PAGE

PRAHEALTHSCIENCES

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorised representatives on the date(s) indicated below, but effective for all purposes as of the Effective Date.

PHARMACEUTICAL RESEARCH ASSOCIATES INDIA PRIVATE LIMITED

By : _____
Authorised Signature

Name : Sachin Narkhede

Title : Associate Director, Clinical Operations

Date : 03/AUG/2017

INSTITUTION

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

By : _____
Authorised Signature

Name : _____

Title : _____

Date : _____

SMO

By : _____

Name : Dr. Sushil Chaudhary

Title : Director

Date : _____

INVESTIGATOR

By : _____

Name : Deepak Bhosle

Title : Principal Investigator

Date : _____

PRAHEALTHSCIENCES

EXHIBIT A
PAYMENT TERMS

Sponsor:	AstraZeneca
Protocol No:	D1680C00019
PRA Project Id:	AZUC1375-CV137

1. **Payee**. The SMO, **Grapecity Research Solutions LLP**, shall be the Payee for this study in accordance with paragraph 2 of this Agreement. It is understood and agreed that although PRA shall direct all payments to SMO, SMO shall disburse any and all payments to Institution and/or Investigator and/or Study Team members as applicable. Pursuant to the Payment Terms, Budget, this Agreement, and in accordance with any applicable agreement between Institution, Investigator and SMO; neither PRA nor Sponsor shall be responsible for any payments directly to Institution, Investigator and SMO.

2. **Subject Recruitment**. Enrollment for this study is competitive. PRA anticipates that the Site and SMO will recruit approximately 2 subjects, but makes no guarantees regarding this number. Site and SMO shall not recruit more, without the prior written approval of PRA or Sponsor, and neither PRA nor Sponsor will be liable for compensation for unauthorized subjects in excess of the number specified above. PRA will advise on recruitment progress and notify sites when recruitment is complete.

3. **Payment Method**. PRA will make payments in Indian Rupee by electronic bank transfer in accordance with Exhibit B Budget as attached. PRA will not make any additional payments to Payee pursuant to this Agreement without the prior written approval of Sponsor. Nor will PRA pay for any procedures performed or treatments given in violation of the Protocol unless approved in writing by Sponsor.

4. **Payment Timing.** PRA will make payments on a quarterly basis, in accordance with Exhibit B Budget. These payments will be made within 45 days of the acceptance criteria outlined below:

   a) **Start-Up Payments**. Upon site activation and the receipt of a completed Payment Information Checklist. Start-Up fees will be paid in accordance with Exhibit B Budget.

   b) **Subject Visit Payments**. PRA will make payments based on subject visits that have been source document verified by Study Monitor, in accordance with Exhibit B Budget. PRA will withhold 10% of each subject visit payment until the Final Payment, as defined below.

5. **Other Payments**. All other payments will be made within the agreed timing, as defined in section 3 above, upon receipt by PRA of a valid invoice, in the amounts specified in Exhibit B Budget, and according to the following criteria.

   a) **IRB Fees or Ethics Committee Fees.** If Site will be using the central IRB or Ethics Committee designated for this Study, PRA will be responsible for the Task Order and fees associated with this service provider. PRA will reimburse the relevant IRB or Ethics Committee for fees in accordance with an invoice issued to PRA by the IRB or Ethics Committee. PRA will not reimburse Site for IRB fees incurred in connection with the Study.

PRAHEALTHSCIENCES

b) **Screen Failures**. PRA will pay for subjects who fail screening based on a pre-determined flat fee. The Site or SMO must document all screening procedures completed prior to screen failure and must ensure that the subject has signed an informed consent form. PRA will not pay for any procedures carried out after the subject has failed screening.

c) **Subject Travel Reimbursement**. PRA will reimburse the Site for subject travel expenses per subject visit in accordance with Exhibit B Budget and the study subject Informed Consent Form.

Invoicing. All invoices must contain the Protocol title and number, a detailed summary of the payment to be made, supporting documents (if any), and be addressed to the following:

PRA Entity Address	**Pharmaceutical Research Associates India Private Limited** ATTN: Accounts Payable The Qube, A-602 and A-603, C.T.S. No. 1498 A/2, M.V. Road, Marol, Andheri (East), Mumbai 400 059
Email	Invoices may be emailed to: PRA Email: investigatorinvoices@prahs.com Protocol Number : D1680C00019

*Invoices missing any of the above information may result in delayed payment.

All invoices should be received by PRA within forty-five (45) days following the incurrence of the applicable expense or database lock, whichever is earlier. Site and SMO understands once PRA has reconciled and closed Study internally that PRA reserves the right to no longer accept invoices.

6. **Final Payment**. PRA will perform a reconciliation of the Site's payments before issuing a final payment to the Payee to account for all previous Study payments, remaining payments due and if applicable this shall include the withholding from Subject Visit Payments and the fair market value of any equipment provided under this Agreement which the Site purchases. The reconciliation will result in either a final payment due to the Payee ("Final Payment") or a request for reimbursement due to PRA ("Reimbursement").

7. **Taxes**. Payments shown in the Exhibit B Budget do not include tax of any type. If the Payee is VAT/GST registered, and if VAT/ GST or other applicable taxes are required under the Payee's country law, the applicable tax should be added and shown on the invoice at the local applicable VAT rate. The Site and Payee each acknowledge and agree that Payee shall be solely responsible for paying the appropriate amount of any applicable federal, state, and local taxes with respect to all payments made pursuant to this Agreement, and PRA shall have no responsibility whatsoever for withholding or paying any such taxes on behalf of the Site or Payee.

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8. **Payment Dispute**. Payee and Institution will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies.

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EXHIBIT B
BUDGET

AstraZeneca
Protocol: AZUC1375-CV1375
Investigational Product: Dapagliflozin, Saxagliptin, or Placebo
Budget Based on Protocol dated: 04-4-17
Investigator: Deepak Bhosle
Study Center: Mahatma Gandhi Mission's Medical College and Hospital
Country: India
Currency: INR - Indian Rupee
Overhead: 20%

Terms Defined

Per Patient Budget – The items in the Budget include all fees payable and will be paid in accordance with the Payment Terms attached to the Agreement.
Section 1. Administrative Costs: costs incurred regardless of patient enrollment or activity. To be paid upon receipt of invoice.
Section 2. Cost Per Visit: costs incurred due to patient activity while participating in the Study and in accordance with the Protocol.
Section 3. Direct Cost: costs incurred due to patient activity and in accordance with the Protocol but are not paid with the Cost Per Visit or by a third party payor. To be paid upon receipt of invoice.

1. Administrative Costs, per invoice

	Unit Cost	Unit Type	Overhead	SubTotal	Total Cost
Start-up Fees	30,000	One time, non-refundable fee	NA	30,000	30,000
Start-up Fee	27,846	One time fee at Initial Payment	5,569	33,415	33,415
Pharmacy Start-up Fee					
PreScreening Fee	1,438	Per completed pre-screen entry up to 200 pre-screen	288	1,726	1,726
Local IRB Fees	Amount invoiced	Recurring fee	NA	Amount invoiced	
Local IRB Review Fee					
Close-out Fees	150,000	One time fee at end of study	30,000	180,000	180,000
Archiving/Document Storage for 15 years (Third Party)				**Estimated Total Administrative Costs:**	**246,141**

All administrative costs will be paid upon receipt of invoice

2. Patient Costs per Visit

	Unit Cost	Unit Type	Overhead	SubTotal	Expected Number of Occurences	Total Cost
Screening	22,538	each	4,508	27,046	1	27,046
Re-Screening (1 re-screen permitted per subject)	22,538	each	4,508	27,046	1	27,046
Lead-In Period	17,451	each	3,491	20,942	1	20,942
Short Term Treatment	26,496	each	5,300	31,796	1	31,796
Day 1	3,978	each	796	4,774	1	4,774
Week 2 Phone	24,934	each	4,987	29,921	1	29,921
Week 6	23,464	each	4,693	28,157	1	28,157
Week 12	16,204	each	3,241	19,445	1	19,445
Week 14	24,934	each	4,987	29,921	1	29,921
Week 20	27,650	each	5,530	33,180	1	33,180
Week 26	25,250	each	5,050	30,300	-	30,300
Early Treatment Discontinuation*	25,250	each	5,050	30,300	-	30,300
Rescue Visit**						
Long Term Treatment	21,510	each	4,302	25,812	1	25,812
Week 32	3,978	each	796	4,774	1	4,774
Week 36	21,510	each	4,302	25,812	1	25,812
Week 40	3,978	each	796	4,774	1	4,774
Week 46	21,787	each	4,358	26,145	1	26,145
Week 52/ETD/Rescue***	3,978	each	796	4,774	1	4,774
Week 56/Followup	3,978	each	796	4,774	3	14,322
Quarterly Phone between Week 56 to Week 104	15,568	each	3,114	18,682	1	18,682
Week 104 Post Study						
Non-Treatment Followup Period	14,757	each	2,952	17,709	-	17,709
NonTx Week 26	14,757	each	2,952	17,709	-	17,709
NonTx Week 52	3,978	each	796	4,774	-	4,774
NonTx Phone Followup	3,978	each	796	4,774	-	4,774
Quarterly Phone between Week 56 to Week 104	15,568	each	3,114	18,682	-	18,682
Week 104 Post Study		**Estimated Total Visit Cost per Patient assuming Treatment through Week 104 (No ET, Rescue, or NonTx):**				**377,323**

Sites will be paid for either Week 26 or ETD depending on the subject's status; not both.
* Subjects who discontinue study medication should have all ETD visit procedures performed and will continue in the study with non-treatment visits and followup.
** Subjects who qualify for rescue should have all rescue visit procedures performed prior to rescue medication is administered and will then continue on treatment from last completed visit. Sponsor will not provide rescue medication or reimbursement.
*** Long-term ETD and long-term rescue visit should follow same guidelines as short-term ETD and short-term rescue visits.

3. Ad Hoc Patient Costs, per invoice

	Unit Cost	Unit Type	Overhead	SubTotal	Total Cost
Screening Failure*	22,538	each	4,508	27,046	27,046
Unscheduled Visit**	28,500	per visit	5,700	34,200	34,200
Travel Reimbursement					
Caregiver Travel Reimbursement	1,385	per travel visit	277	1,662	1,662
Patient Travel Reimbursement	600	per travel visit	120	720	720
Rescue Medication and/or Background Therapy Reimbursement					
3mL Vial	1,677	per vial	335	2,012	2,012
Conditional Procedures					
Urine Pregnancy Test (females of childbearing potential only); At home test provided and should be used on days specified in protocol	326	each	66	392	392
Serum Pregnancy Test (females of childbearing potential only)	300	each	60	360	360
Repeat Laboratory Analysis (may be repeated once per subject; initial sample costs included in the visit total of all applicable visits as indicated in protocol and should not be invoiced additionally)					
Venipuncture plus handling to central laboratory for analysis (must be performed within 10 days from original Screening Visit)	2,229	each	446	2,675	2,675

All Direct Costs will be paid upon receipt of invoice
*Screen Failures will be reimbursed as a ratio of 3 per 1 randomized subjects; no site maximum limit
**Procedures completed at an unscheduled visit will be paid upon receipt of itemized invoice up to a maximum as defined by the unit cost plus any conditional items completed

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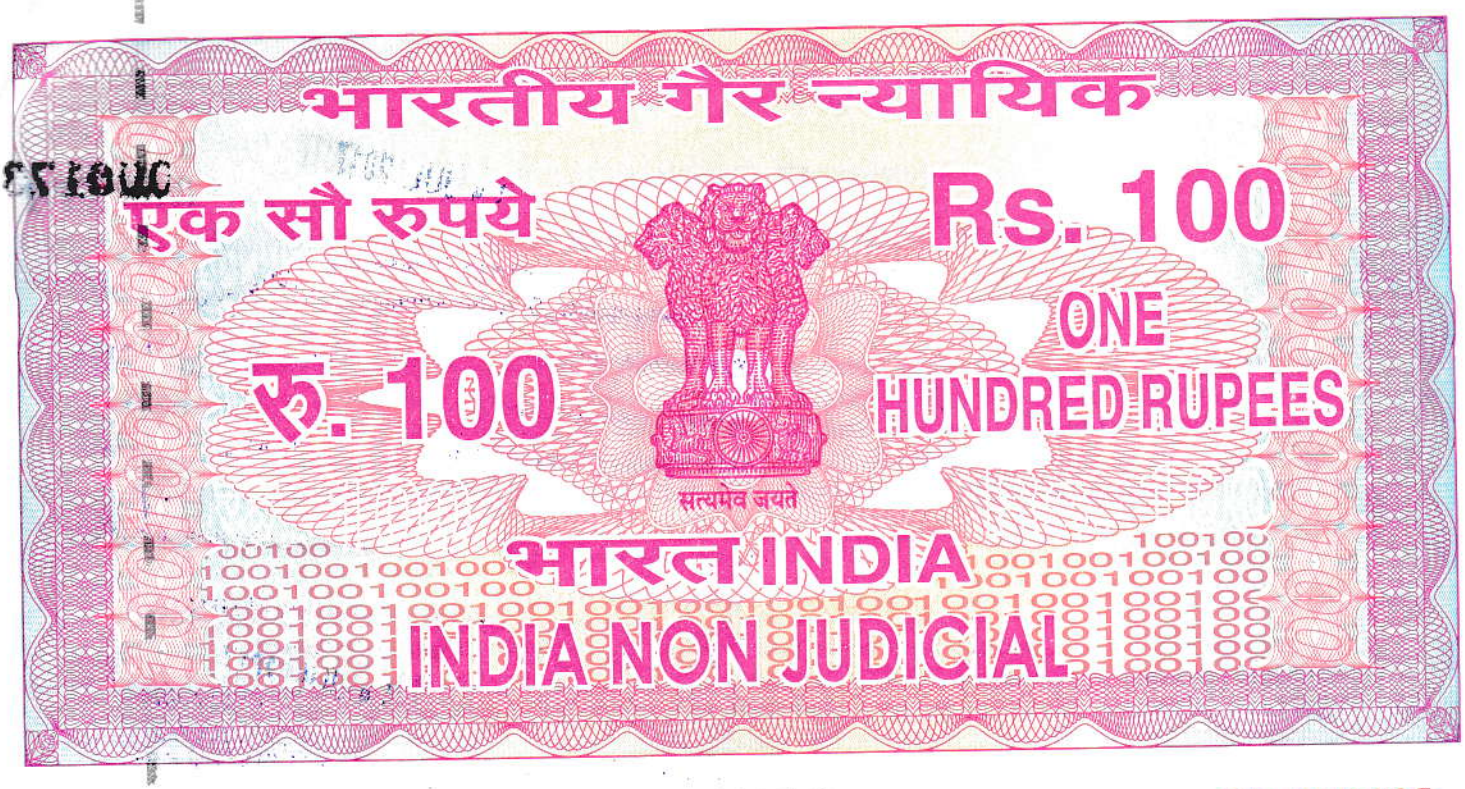
EXHIBIT C
EQUIPEMT TO BE PROVIDED

1. -70 Freezer
2. Minimum-maximum thermometer
3. -70C Freezer thermometer
4. Filing cabinet



महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ SD 028225

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.वि.क. 4000095
-7 JUL 2017
सक्षम अधिकारी

CLINICAL TRIAL SERVICE AGREEMENT

श्री. प्र. ना. चिंचघरे

DATED 14TH DAY OF JULY 2017

BETWEEN

GLENMARK PHARMACEUTICALS LIMITED

AND

MAHATMA GANDHI MISSIONS MEDICAL COLLEGE AND HOSPITAL

AND

DR. DEEPAK BHOSALE

AND

GRAPECITY RESEARCH SOLUTION LLP

INPLCT155 42

14 JUL 2017

000174

जोडपत्र - १ Annexure - I

प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव _____

मुद्रांक विकत घेणाऱ्याचे रहिवाशी पत्ता _____

मुद्रांक विक्रीबाबतची तोंद पटी अशा तपशील _____ दिनांक _____

Glenmark Pharmaceuticals Ltd.
Glenmark House, B D Sawant Marg,
Chakala, Off Western Express Highway,
Andheri - (E), Mumbai - 400099

मुद्रांक विकत घेणाऱ्याची सही

परवानाधारक मुद्रांक विक्रीची सही

परवाना क्रमांक : ८०००९५

मुद्रांक विक्रीचे ठिकाण/पत्ता : अंधेरी कोर्ट बार असोसिएशन

एम. एच. कोर्ट, अंधेरी रेल्वे स्टेशनच्या बाजू

अंधेरी (पूर्व), मुंबई - ४०० ०६९

14 JUL 2017

टीप : सदर मुद्रांक हा केवळ न्यायालयीन प्रतिज्ञापत्र सादर करणेसाठी
वापरणेत यावा. (महाराष्ट्र अधि. नि. ०१/०७/२००४ कलम)
सदर मुद्रांकाची उर्वरीत मुद्रांक खरेदी करुन त्यांची त्वरीत वापरणेसाठी मुद्रां
वेंडरकडून घेणेबाबत योग्यरीत्या अंमलबजावणी करावी.

CLINICAL TRIAL SERVICE AGREEMENT

This Clinical Trial Service Agreement ("**Agreement**") is made on this 14th day of July 2017

Between

Glenmark Pharmaceuticals Limited, a company incorporated under the laws of India having its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai – 400 026, India and its corporate office at Glenmark House, B. D. Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, India (hereinafter referred to as "**Glenmark**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **FIRST PART**;

And

Mahatma Gandhi Missions Medical collage and Hospital an institution incorporated under the laws of India having its registered office at N-6, CIDCO, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Institution**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **SECOND PART;**

And

Dr. Deepak Bhosale, aged around 41 years, Indian, residing at Flat No 201, Regency Royal, surana Nagar, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Investigator**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **THIRD PART.**

And

Grapecity research Solution LLp., a firm having address at Prakash Housing Society, Block No 2, Thergaon , Pune, Maharashtra, India (hereinafter referred to as the "**SMO** " which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **FOURTH PART.**

"Glenmark", "Institution", "SMO" and Investigator" are hereinafter collectively referred to as the "Parties" and severally as a "Party".

WHEREAS:

Glenmark is *interalia* engaged in the business of discovery, development, manufacturing, distribution and sales of pharmaceutical products;

The Institution is a private and is *interalia* engaged in in carrying out clinical trials;;

The Investigator is engaged in carrying out clinical research/studies/trials;

The SMO is a site management organization engaged in carrying out various activities during a clinical trial;

Glenmark has approached the Institution and the Investigator to provide the Services in accordance with the provisions herein below which the Institution and the Investigator are willing to provide on the terms and subject to the conditions of this Agreement;

Pursuant to the aforesaid, the Parties are desirous to spell out the terms and conditions in writing to give effect to the aforesaid understanding.

IN CONSIDERATION OF THE PAYMENTS AND MUTUAL PROMISES AND COVENANTS CONTAINED HEREIN AND WITH THE INTENT TO BE LEGALLY BOUND HEREBY, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. **GENERAL DEFINITIONS & INTERPRETATION**

In this Agreement the following capitalised terms shall, unless the context requires otherwise, have the following meanings:

1.1. "**Adverse Event**" means any untoward medical occurrence in a patient or clinical investigation Subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An Adverse Event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) Product;

1.2. "**Commencement Date**" means the date on which the Investigator commences its activities in accordance with this Agreement;

1.3. "**Confidential Information**" means the proprietary and/or confidential information of any Party, howsoever disclosed, which relates to the subject matter of this Agreement including without limitation technical information, business information, information relating to the conduct of the Trial, the Subjects of the Trial, Trial Material, Know-How, methodology, trade secrets, results, processes, sequences, structure and organization of the Trial, the Protocol, the Trial Materials and information relating to the Investigational Products etc. and information included within this definition by virtue of Sections 10 and 13;

1.4. "**Consent Form**" means the patient information sheet & consent form required to be voluntarily completed by every Subject/Patient participating in the Trial (and/or a relative or legal guardian of the Subject or any other person or authority required by law at each Site) after having been informed of all aspects of the Trial. The Consent Form shall be approved by Glenmark and Ethics Committee prior to use at the Site;

1.5. "**Co-investigator**" means one or more resident doctors / consultants with the Institution appointed by the Investigator at each Site as per the provisions of law and approved by Glenmark; who will lead, co-ordinate and run the Trial at the Site;

1.6. "**CRF**" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Glenmark on each Trial Subject/Patient;

1.7. "**Eligible Subject**" means a person who meets all the eligibility criteria as set out in the Protocol for enrolment of a subject/patient into the Trial at the time of selection;

1.8. "**Ethics Committee**" means the ethics committee/independent review board constituted according to GCP and local laws and regulations and having authority over the conduct of any clinical Trial at the Site and that is ultimately responsible for approving the conduct of the Trial and associated Protocol;

1.9. "**GCP**" means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected;

1.10. "**ICH**" means the International Conference on Harmonisation. The Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) specifies the unified standards to facilitate the mutual acceptance of clinical data by the regulatory authorities of Europe, Japan and North America together with such other good clinical practice requirements as are specified in Directive

2001/20/EC and Directive 2005/28/EC or the Code of Federal Regulations relating to medicinal products for human use and as may otherwise be applicable in the territory where the Site is located;

1.11. "**Ineligible Subject**" means a person who does not meet the eligibility criteria as set out in the Protocol for enrolment of a subject into the Trial;

1.12. "**Inspection(s)**" means the act by a Regulatory Authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical Trial and that may be located at the Site of the Trial, at Glenmark's facilities, or at other establishments deemed appropriate by the Regulatory Authority(ies);

1.13. "**Investigational Product**" means a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use;

1.14. "**Investigator**" shall have the same meaning as assigned herein above and who shall be responsible for the conduct of the clinical Trial at a trial Site;

1.15. "**Intellectual Property Rights**" means all intellectual property rights throughout the world (both present and future) including without limitation copyrights, trademarks, designs, patents, database rights, Know-How and all other rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them for their entire term and any applicable extensions;

1.16. "**Know-How**" means all technical and other information which is not in the public domain including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to Regulatory Authorities;

1.17. "**Protocol**" means the document that describes the objective(s), design, methodology, statistical considerations, and organization of the Trial as more specifically laid down in **Annexure 1** hereto and shall include amendments (written description of a changes(s) to or a formal clarification of a Protocol) made by Glenmark at its sole discretion from time to time;

1.18. "**Regulatory Authority**" means any governmental or regulatory authority responsible for granting health approval, clinical trial authorisations and licences, import and/or export licences or any other relevant approval, permission or licence necessary for the conduct of a trial and those that conduct Inspections of sponsors, contract research organisations, Sites/Institutions/Investigators etc.;

1.19. "**SAE**" means any untoward medical occurrence that at any dose that: results in death, is life threatening (actual or hypothetical), requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a medically significant event;

1.20. "**Services**" means and includes the services to be performed according to the terms of this Agreement and the Protocol by the Investigator directly or through the Institution, Co-investigator etc. and conduct and performance of the Trial pursuant to ICH GCP and as more fully outlined in **Annexure 2** hereto;

1.21. "**Site**" means the location(s) where Trial related activities are actually conducted;

1.22. "**Site File**" means the file maintained by Investigator at each Site and the file maintained in-house by Glenmark containing the documentation specified in Section 8 of ICH GCP or as may otherwise be required by any other local rules, laws, regulations, directives or guidance;

1.23. "**Subject**" means a person who is enrolled in the Trial as an Eligible Subject and a recipient of the Investigational Product;

1.24. "**Termination Date**" means the date when the Parties have performed their respective obligations under the Agreement or if terminated earlier in accordance with the terms and conditions of this Agreement, then such earlier date;

1.25. "**Trial/Study**" means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms Trial and Study are synonymous;

1.26. "**Trial Materials**" means the Investigational Product, the Protocol, case report forms, Consent Forms, placebos, trial aids, and any other material that is used in, or arises out of, the conduct of the Trial;

1.27. Headings used or mentioned in this Agreement are for convenience only and do not affect the interpretation of the sections;

1.28. In this Agreement unless the context requires otherwise:

1.28.1. words importing the singular include the plural and vice versa and reference to one gender includes all genders;
1.28.2. reference to any individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa;
1.28.3. any phrase introduced or preceded by the terms "include", "including" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding these terms unless preceded by the term "explicitly".

1.29. Recitals and Annexures hereto constitute an integral part of this Agreement.

2. TERM

2.1. This Agreement shall come into force on the Commencement Date and shall remain valid until the Termination Date.

3. GENERAL OBLIGATIONS OF THE INSTITUTION & INVESTIGATOR

3.1. The Institution and the Investigator hereby represents and warrants that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct the Services to the highest of the professional Standards mentioned **Annexure 3** and in accordance with this Agreement.

3.2. Throughout the Term the Institution and the Investigator shall:

3.2.1. provide the Services as per the terms of this Agreement and as more fully outlined in **Annexure 2** hereto;

3.2.2. appoint appropriate and professionally trained, experienced and qualified personnel at their sole responsibility, risk and cost to perform the Services under this Agreement;

3.2.3. use all reasonable endeavours to ensure the smooth running of the Services at all times as per the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4;**

3.2.4. will ensure that all employees/study team perform the Services in accordance with the terms of this Agreement and the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4:**

3.2.5. provide the data required by Glenmark pursuant to and in furtherance of the Services;

3.3. The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct monitoring/audit at such intervals as required by Glenmark of all Services provided by the Institution and the Investigator under this Agreement including all records and documents relating to the Services, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and the Institution and the Investigator will provide such assistance as reasonably requested by Glenmark in connection therewith.

3.4. The Institution and the Investigator will immediately notify Glenmark of any notified Inspections affecting or potentially affecting the Services provided to Glenmark.

4. GENERAL RESPONSIBILITIES

4.1. Glenmark shall assist and support the Institution and the Investigator in its performance of the Services as more particularly laid down in Annexure 2 hereto.

4.2. The Parties understand and agree that the Investigator may from time to time appoint the SMO to assist him in carrying out the Services (or any part thereof).

5. GENERAL OBLIGATIONS OF THE PARTIES

5.1. Parties understand, acknowledge and agree that they will work together and co-operate with the other in order to comply, as closely as possible, with the estimated Trial timeline annexed hereto as **Annexure 4**.

5.2. Parties further understand, acknowledge and agree that prior to or at any time during the course of the Trial, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

5.2.1. The Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site monitoring and audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

5.2.2. Parties will negotiate in good faith any amendments do modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

5.3. Should there be any inconsistency between the Protocol and the other terms of this Agreement, the terms of the Protocol shall prevail to the extent of such inconsistency.

6. PAYMENT

6.1. In consideration of the performance of the Services by the Institution and the Investigator pursuant to this Agreement, the Institution and Investigator have requested Glenmark to make the payments to the SMO, and Glenmark has agreed to make payments to the SMO as per **Annexure 5** hereto. The SMO shall submit to Glenmark for payment, pursuant to the following terms, an invoice for those sums identified in **Annexure 5** when the relevant event or time period set out in **Annexure 4** occurs.

6.2. Glenmark will pay the SMO all sums properly invoiced in accordance with Section 6.1 and **Annexure 5** within 30 days of receipt of such invoice.

6.3. Glenmark may suspend payment of an invoice if it raises a bona fide dispute as to the accuracy of any invoice submitted by the SMO. If the dispute cannot be resolved between the Parties it will be referred to arbitration in accordance with Section 17.2.

7. INDEMNIFICATION

7.1. The Institution and the Investigator hereby jointly and severally undertakes to indemnify, defend and hold Glenmark, its successors and assigns, its officers, directors, employees harmless agents against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred by it on its own account or any third party claim, action or proceeding to which Glenmark may be subject which arises out of or results from or may be payable by virtue of:

7.1.1. any failure of the Institution, Investigator, its affiliates, contractors or agents, Co-Investigator, to perform the Trial in accordance with the Protocol, ICH-GCP, local regulatory requirements; and/or

7.1.2. improper or negligent administration or use of the Investigational Product during the course of the Trial ; and/or

7.1.3. any breach of Section 10 and/or 13 or other terms of this agreement; and/or

7.1.4. any negligence, misconduct, malpractice, material deviation, breach or non-compliance of any provisions of this Agreement by the Institution and/or the Investigator, its affiliates, contractors or agents, Co-Investigator, the project manager and the SMO; and/or

7.1.5. due to infringement of the Intellectual Property Rights of Glenmark or a breach of any warranty, representation, covenant or obligation.

7.2. Notwithstanding the above, Glenmark shall assume no liability for any case in which written informed consent and an authorization regarding personal data in accordance with applicable law was not given by the patient involved Protocol amendments (if any) were not approved by the Regulatory Authority.

7.3. Glenmark hereby undertakes to indemnify Institution, Investigator, its affiliates, contractors, agents or the Co-Investigator against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, arising out of, or in connection with, any injury to a person (including death) arising solely from the Investigational Product due to negligence of Glenmark, except to the extent the same is caused by the negligence, misconduct, malpractice or breach or non-compliance by the Institution and/or the Investigator, Co-Investigator or its officers, directors, employees or agents of the terms of the Protocol, the terms of this Agreement or any applicable laws, regulations, guidelines and generally accepted standards.

7.4. Any Party hereto seeking indemnification for itself or on behalf of those other parties specified hereunder ("**Indemnified Party**") shall notify the other Party ("**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party of any claim under the indemnity or allegation by a third party in respect of which the Indemnified Party intends to base a claim for indemnification hereunder ("**Claim**"), but the failure or delay so to notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected by such unreasonable delay or failure.

7.5. The Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim to assume the defence or handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 7.6 below shall govern.

7.6. The Indemnifying Party shall select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim, and the Indemnifying Party shall keep the Indemnified Party reasonably apprised of the status of such Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which leads to liability or creates any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to full indemnification hereunder. The Indemnified Party shall fully cooperate with the Indemnifying Party and shall be entitled to appoint its own counsel to observe and report on but not participate in the Claim at its own expense. Notwithstanding the foregoing, in the event the Indemnifying Party fails to conduct the defence or handling of any Claim in good faith after having assumed such defence or handling, then the provisions of Section 7.8 below shall govern.

7.7. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim, of the Indemnifying Party's election to assume the defence or handling of such Claim, the provisions of Section 7.8 below shall govern.

7.8. Subject to Sections 7.5, 7.6 and 7.7, the Indemnified Party may, at the Indemnifying Party's expense, select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall fully cooperate with the Indemnified Party and shall be entitled to participate in the defence or handling of such Claim with its own counsel and at its own expense.

7.9. The Indemnified Party will only be entitled to claim under the indemnity for a Claim provided that it has not made any admission of liability or culpability without having first obtained the prior written consent of the Indemnifying Party.

8. LIMITATION OF LIABILITY

8.1. Save for the provisions of Section 8.2 below, notwithstanding any other provision in this Agreement, in no event shall either Party be liable, whether in contract, tort, under an indemnity, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof. However, it is understood and agreed that claims, actions, lawsuits or other proceedings made by third parties being the subject of the indemnification obligation under Section 7 shall not be considered as indirect, consequential, special or incidental damages.

8.2. Nothing in this Agreement will act as or seek to restrict, limit or exclude any liability for (i) death or personal injury caused by negligence; (ii) liability for fraud or fraudulent misrepresentation; (iii) negligence or misconduct; or (iv)any liability for breach of implied undertakings or conditions which cannot be excluded or limited by contract.

9. INSURANCE

9.1. Institution and the Investigator shall secure and maintain in full force and effect throughout the performance of the Trial insurance or self-insurance coverage for medical malpractice and general liability in amounts appropriate to the conduct of his/her business. Institution and the Investigator shall also require any subcontractor to secure and maintain such coverage for his/her/its activities related to the Trial. Certificates evidencing such insurance will be made available for examination upon request by Glenmark.

10. CONFIDENTIAL INFORMATION AND PUBLICITY

10.1. All data, documents and information whether written or orally supplied or disclosed by Glenmark to the Institution and/or the Investigator, including but not limited to Confidential Information and the Materials, Documents and all other data including that derived from the Services, in whatsoever form, shall be the exclusive property of Glenmark and shall be treated as strictly confidential and shall not be disclosed to any person except to the extent that any such disclosure is necessary to be disclosed to that person in connection with the proper performance of this Agreement. The Parties understand, acknowledge and agree that all results and data from the Services in whatever form are the exclusive property of Glenmark and cannot be:

10.1.1. used by the Institution and/or the Investigator or its Co-Investigators, agents, employees or consultants etc. other than pursuant to the performance of the Services; or,

10.1.2. disclosed by Institution and/or the Investigator or its Co-investigators or any of its employees, agents, personnel etc. to any person including directly or indirectly to any person other than Glenmark or to persons who are authorised, in writing by Glenmark in advance, to receive such information.

10.2. The Institution and/or the Investigator will take all precautionary measures to ensure compliance of this Section 10 by its employees, agents, consultants and personnel to whom Confidential Information is required to be disclosed under the terms of this Agreement. The Institution and/or the Investigator will ensure that all its employees, agents, consultants, and personnel are bound by obligations no less onerous than those contained herein before any disclosure of such Confidential Information to them.

10.3. A breach of this Section 10 by the Investigator or any of the Investigator's agents, employees or contractors shall constitute a material breach by the Investigator of this Agreement.

10.4. The restrictions and obligations under this Section 10 shall not apply to any information which:

10.4.1. at the time of disclosure, is freely and lawfully in the public domain or thereafter lawfully becomes part of the public domain;

10.4.2. is in the possession of the Institution and/or the Investigator prior to the first disclosure of such information by Glenmark or its agent and the Investigator and Institution are not under any obligation of confidence in respect of such information;

10.4.3. other than pursuant to the Services, is independently and without any reference (whether direct or indirect) to the Confidential Information generated by the Investigator and/or Institution as can be demonstrated by contemporaneous written documents without any obligation of confidence owed in respect of such new information;

10.5. In the event the Institution and/or the Investigator must disclose in order to comply with an applicable mandatory and enforceable legal obligation or to the extent ordered by a court of competent jurisdiction exercising its right of authority over the Institution and/or the Investigator (subject to entry of an appropriate protective order), provided that if the Institution and/or the Investigator is required by such law, regulation or order to make any such disclosure of Confidential Information, they shall give reasonable notice to Glenmark of such disclosure requirement and will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed.

10.6. Any inventions or improvements whether patentable or unpatentable which are conceived of, discovered, or developed by the Institution and/or the Investigator, its Affiliates or by any person claiming through them in any way derived from, related to, based on, or resulting from the use of the Confidential Information ("Derivative Intellectual Property") shall be promptly disclosed to Glenmark. Any such Derivative Intellectual Property shall be the sole property of Glenmark. The Institution and/or the Investigator, its affiliates and any person claiming through them shall do all acts and things as shall be necessary to vest all right, title and interest therein in Glenmark. The Institution and/or the Investigator shall keep the said Derivative Intellectual Property confidential

in accordance with this Agreement. The Institution and/or the Investigator therefore undertakes that they will not reverse engineer, decompile or dissemble the Confidential Information or make any variant out of the Confidential Information and strictly use or abide by the terms of this Agreement.

10.7. Notwithstanding the performance or the discharge for whatever reason including breach of this Agreement, the provisions of this Section 10 shall remain in full force and effect in perpetuity.

10.8. Institution and the Investigator will preserve all Confidential Information including periodic backup of computer files, to prevent the loss or alteration of Glenmark's study data, documentation, and correspondence. At Glenmark's request or on expiry or upon termination of this Agreement, the Investigator and Institution shall return all the Confidential Information received in pursuance to this Agreement including all information disclosed orally and shall also destroy or erase all the electronic files, copies, notes, memorandum, extracts, which contains, reflects or is derived from the Confidential Information of Glenmark.

11. **REPRESENTATIONS AND WARRANTEES**

11.1. Each Party represents, warrants and covenants for itself to the other that:

11.1.1. it has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this Agreement;

11.1.2. it has the power and authority to enter into and perform its obligations under this Agreement;

11.1.3. this Agreement has been duly authorised, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

11.1.4. neither the execution and delivery of this Agreement, nor the performance by such Party of its obligations hereunder nor compliance by such Party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any other agreement, indenture, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such Party.

11.1.5. it will perform its obligations hereunder in accordance with all applicable federal, international, state or local law or regulation.

11.2. The Institution and Investigator represent and warrant that they will not enter into any other agreement(s) which would interfere or prevent performance of the obligations described herein.

11.3. The Institution and Investigator represents and warrants that they have the facilities, professional, technical and clerical staff, experience and expertise sufficient in quality and quantity to perform the Services and the Trial pursuant to the Protocol within the time frame set forth herein.

11.4. Debarment Certification: the Investigator and Institution jointly and/or severally represent and warrant that the Investigator, its employees, the Co-Investigator and/or any agents, contractors, sub-contractors etc. carrying out any of the Services have not been debarred under any law. In the [illegible]

[illegible]

11.5. Compliance with Laws: the Institution and Investigator represent and warrant that all the Services performed and provided by the Institution and Investigator, the Co-Investigator and/or any agent, contractor, sub-contractor shall fully comply with all applicable central, state, and local laws, rules and/or regulations, as may be amended from time to time.

11.6. Inconsistent Obligations: the Institution and Investigator represent and warrant that the responsibilities and obligations assumed by the Institution and Investigator on behalf of Glenmark hereunder are not in conflict with any other obligations the Institution and Investigator may have.

11.7. Save for those express warranties set out herein, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to its obligations, duties or activities owed or performed under this Agreement and hereby excludes any other such express or implied warranty in respect of that subject matter.

12. DEFAULT AND TERMINATION

12.1. For the purpose of this Section 12 each of the following constitutes an event of default ("Default"):

12.1.1. If any Party breaches any of its obligations under this Agreement and fails to remedy the breach within 30 days of written notice being given by the other Party identifying and requiring that breach to be remedied;

12.1.2. if a Party becomes insolvent, is dissolved or makes a general assignment for the benefit of its creditors, has a receiver appointed for a substantial part of its assets or makes the requisites filings as a sick company before the relevant authorities;

12.1.3. if conducting the Services becomes prohibited by law, rule, regulation or any amendment thereof.

12.2. Either Party may immediately terminate this Agreement by notice in writing to the other Party if a default by that other Party occurs.

12.3. Without prejudice to any other rights Glenmark may have, Glenmark may terminate this Agreement immediately by written notice if, in the reasonable opinion of Glenmark, any of the following events occurs:

12.3.1. there is unsatisfactory progress of the Services and/or Trial;
12.3.2. if patient recruitment is not initiated within 60 days of Site initiation;

12.3.3. Any Co-Investigator ceases to be employed by or engaged in the performance of a Trial at any Site;

12.3.4. there is breach of Section 10 or 13 of this Agreement by the Institution and/or Investigator or any employee, director, agent, contractor, sub-agent, sub-contractor, the Co-Investigator or any other person appointed by or under control of or claiming through the Investigator;

12.3.5. there is an inability to recruit an adequate number of Subjects within the prescribed period as advised at the time of commencement;

12.3.6. there occur Adverse Events with the conduct of the Trial which in necessitate the discontinuance of the Trial;

12.4. Glenmark may terminate this Agreement upon 30 days prior written notice without cause.

12.5. On termination or expiry of this Agreement for any reason whatsoever Institution and the Investigator:

12.5.1. will deliver to Glenmark all Investigational Product, Trial Materials within 14 days of the date of termination or expiry;

12.5.2. will return any sums paid for Services which have not been performed before the date of termination or expiry;

12.5.3. will co-operate with Glenmark and do everything necessary to bring about the orderly termination of all Services;

12.6. On termination or expiry of this Agreement for any reason , Glenmark will pay for all Services performed by the Institution and the Investigator to the satisfaction of Glenmark in compliance with this Agreement ;

12.7. Each Party will be regarded as discharged from any further obligations under this Agreement except for those expressed to survive termination or expiry.

12.8. The termination of this Agreement pursuant to this Section 12 will not affect the rights of either Party in respect of any antecedent breach of this Agreement. Further, in the event of any termination of this Agreement on account of a Default under Section 12.2, the non-breaching Party shall have the right to recourse to such remedies that may be available to them at law or in equity.

13. **INTELLECTUAL PROPERTY**

13.1. Institution and the Investigator acknowledge and agree that Glenmark is the sole owner of all the Intellectual Property Rights as defined herein above and this Agreement does not grant, transfer or assign to the Institution and the Investigator any legal right or beneficial ownership in any Intellectual Property Rights of Glenmark.

13.2. Institution and the Investigator further acknowledge and agree that all rights to any discovery or invention conceived or reduced to practice in the direct performance of the Study conducted under this Agreement in accordance with the Protocol will belong to Glenmark. Institution and the Investigator agree to assign to Glenmark, at the request of Glenmark, the sole and exclusive ownership thereto, upon the payment of costs by Glenmark, if any, incurred by Institution and the Investigator in the filing, prosecution, or maintenance of any patent application or patent issuing thereon. Such application, if any, will be filed and prosecuted by Glenmark. Institution and the Investigator will promptly disclose to Glenmark any invention or discovery arising under this Agreement

13.3. All Intellectual Property and other data of Glenmark which the Institution and the Investigator may gain or have access to pursuant to this Agreement shall remain the property of Glenmark.

13.4. The Institution and the Investigator will not use Glenmark's name, trademark or brand in any publicity, advertising or news release without the prior written consent of Glenmark. For the avoidance of doubt, this restriction does not apply to the inclusion in documents of or use of Glenmark's name for the proper performance of the Services under this Agreement.

13.5. The Institution and the Investigator agree that all Intellectual Property Rights and Know-how arising from conduct of the Services belong to and vest in Glenmark and that the consideration payable hereunder shall be sufficient consideration towards the same.

13.6. The Institution and the Investigator hereby undertake to assign and to procure the assignment of all Intellectual Property Rights and to the extent possible all Know-how arising out of the performance of the Services in Glenmark to the extent the same are not automatically assigned by virtue of this Agreement. Institution and the Investigator agree to execute all other documents

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Dr. Reddy's Laboratories Ltd.
Dr. Reddy's Laboratories Ltd.

MUMBAI 400099. GLENMARK PHARMACEUTICALS LTD.

13.7. The Institution and the Investigator agree to co-operate regarding a reasonable request of Glenmark or to procure the assistance from another person or entity involved in the Services as may be required in any patent filings Glenmark deems necessary.

13.8. The Institution and the Investigator will not infringe the intellectual property rights of a third party or misappropriate any know-how or intellectual property rights of a third party in performing the Services.

13.9. Upon expiry or termination of this Agreement, the Institution and the Investigator shall stop using, return forthwith all the Intellectual Property Rights to Glenmark and restrain from using any Intellectual Property Rights.

14. PUBLICATION RIGHTS

Glenmark has the exclusive right to authorize any and all publications and/or communications relevant to the Trial/Study and Investigator undertakes to make no presentations or publications of the results of the Trial/Study without the prior written approval of the Glenmark with regard to the content and the timing of said presentations or publications. When permission for presentation or for publication is granted, Institution and Investigator agrees that, prior to submission of a manuscript or abstract to the publisher, Institution and or the Investigator shall forward a copy of said manuscript or abstract to the Glenmark for its written approval

15. RELATIONSHIP OF PARTIES

15.1. Glenmark, Institution and the Investigator have entered into this Agreement as independent contractors and nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the Parties.

15.2. The Institution and the Investigator acknowledge and agree that the Institution and the Investigator are responsible for all the employees and all other personnel deputed by the Institution and the Investigator to conduct Services covered by this Agreement and a breach by any such person of the terms of this Agreement shall constitute a breach by the Institution and the Investigator of the same terms of this Agreement.

16. FORCE MAJEURE

16.1. A Party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any cause beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, war, insurrection, civil strife, riots and government action which materially affects a Party's ability to perform its obligations under this Agreement. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure occurrence, shall be automatically extended for a period of time equal to the period of such disability. The Service Provider shall immediately notify Glenmark if, by reason of any of the disabilities referred to herein, the Institution and the Investigator is unable to meet any specified deadline or time for performance.

16.2. In the event that any part of the Services is rendered invalid as a result of such disability, the Institution and the Investigator shall, upon written request from Glenmark, repeat that part of the Services affected by the disability. Provided, however, that if a Force Majeure Event continues for more than 2 months, a Party may terminate this Agreement by giving at least 15 days notice to the other Parties.

17. GOVERNING LAW / ARBITRATION

17.1. This Agreement is entered into and will be deemed for all purposes to be governed and construed in accordance with the laws of India.

17.2. All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be finally settled under the Indian Arbitration and Conciliation Act, 1996 by a sole arbitrator to be appointed in accordance with the said Act. The place of the arbitration shall be Mumbai. The language of the arbitration proceedings shall be English. Except as otherwise required by law, for the purposes of enforcement or any applicable stock exchange rules and regulations, the arbitral proceedings and the award shall not be made public without the joint consent of the Parties hereto and each such Party shall maintain the confidentiality of such proceedings or the award and such shall be deemed to be Confidential Information.

18. **NO WAIVER**

18.1. Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any party thereafter to enforce each and every provision of this Agreement.

19. **SEVERABILITY**

19.1. Should one or more provisions of this Agreement be or become invalid or unenforceable, the parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

20. **ASSIGNMENT**

20.1. Neither Party shall assign or sub-contract this Agreement or part or all of its obligations herein without the prior written consent of the other Parties. Any Party, which does sub-contract, as permitted with the other Parties consent will remain responsible for the acts and omissions of its sub-contractors as though they were its own.

21. **AGREEMENT AND AMENDMENT**

21.1. Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.

21.2. This Agreement including its Annexures contains the entire understanding between the Parties and supersedes all other negotiations representations and undertakings whether written or oral of prior date between the Parties relating to the Services that are the subject of this Agreement.

22. This Agreement is made in English in more than one copy each of which shall be deemed to be an original and may have been translated to another language. All such copies are valid and in case of any discrepancy, English text will prevail over other languages.

23. **THIRD PARTY RIGHTS**

23.1. Nothing in this Agreement is intended to confer on any third party any right to enforce any term of this Agreement.

24. **SURVIVAL OF OBLIGATIONS**

24.1. The agreements, covenants and obligations set forth in Sections 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 24 shall continue to be binding upon the Parties hereto and shall survive any termination or expiry of this Agreement. Any other terms of this Agreement which are either expressed so as to survive (or are capable of surviving) expiry, or termination of this Agreement or from their nature or context it is contemplated that they are to survive expiry or termination, shall remain in full force and effect notwithstanding any expiry or earlier termination of this Agreement.

MUMBAI 400099.

25. NOTICES

25.1. All notices required or permitted under this Agreement shall be in writing and shall be deemed delivered when delivered in person or by fax or five (5) days after the date postmarked if sent by registered or certified mail or courier, return receipt requested, postage prepaid, addressed as follows:

If for Glenmark Pharmaceuticals Limited:

B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai – 400026, India and its corporate office at Glenmark House, B D Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, India

If for the Institution: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India

If for the Investigator: Dr. Deepak Sadashiv Bhosle, Flat No 201, regency Royal, Surana Nagar, Aurangabad-431003, Maharashtra, India.

If for the SMO: Grapecity research Solution LLP, Prakash housing society, Block No 2, Thergaon, Pune, Maharashtra, India

25.2. A Party may change its address from time to time by providing written notice to the other Parties in the manner set forth above.

(Signature Page to follow)

MBAI 400099. GLENMARK LTD.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed.

For Glenmark Pharmaceuticals Limited

Name: Suyog Shetty
Title: General Manager - Legal

For the Institution

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Name: Dr Rajendra Bohra
Title: Dean,

Investigator

Name: Dr Deepak sadashiv Bhosle
Title: Principal Investigator

For SMO

Name: Dr Sushil Chaudhary
Title: Director

ANNEXURE 1

PROTOCOL

The Protocol title and protocol number are as follows:

Protocol Title: Ref: "A 24-week, randomised, double-blind, double-dummy parallel-group, multi- centre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type-2 diabetes mellitus.

Sub: Clinical Trial Agreement

Protocol Number: **GPL/CT/2016/009/III**

Clinical Trial Phase: III

Protocol has already been provided to the Investigator separately and will form an integral part of this Agreement.

ANNEXURE 2

Description of Responsibilities

1. OBLIGATIONS OF THE INSTITUTION AND THE INVESTIGATOR

The Institution and Investigator hereby represent and warrant that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct Trial to the highest of the professional standards and in accordance with this Agreement, the Protocol, ICH GCP and all applicable standard operating procedures.

1.1 Throughout the Term the Investigator shall:

1.1.1 appoint appropriately and professionally trained, experienced and qualified personnel to perform the Services under this Agreement;

1.1.2 appoint the Co-investigators who meet the conditions stipulated in **Annexure 6**, time to time review eligibility of such Co-investigators and discontinue/remove those Co-investigators from further conducting the Trial who no longer meet those conditions;

1.1.3 use all reasonable endeavours to ensure the smooth running of the Trial at all times as per the Protocol and time lines mentioned in **Annexure 4** and will ensure that the Co-investigator performs the Trial in accordance with the terms of this Agreement, the Protocol and as per the provisions of all laws and practices applicable;

1.1.4 act professionally and responsibly as the necessary interface between the Co-investigator, Institution, Site and Glenmark;

1.1.5 collect all information and data required by Glenmark pursuant to and in furtherance of the Trial;

1.1.6 immediate reporting to Glenmark in accordance with the SAE reporting plan on becoming aware of any SAEs at the Sites;

1.1.7 fully co-operate with Glenmark throughout the Term and even thereafter in respect of the performance of the Services and compilation and use of information and data generated from the Trial and follow all directions and instructions relating to the Trial provided by Glenmark;

1.1.8 use all reasonable endeavours to ensure that the Trial is planned, performed and concluded within the estimated Trial timeline as per the projection.

1.1.9 Where required as explicitly informed by Glenmark, nominate for Glenmark's approval an appropriate number of Co-Investigators for the Trial and keep Glenmark and Institution and its personnel at the Site notified of the contact details of the respective Co-Investigator (including an emergency number) allocated responsibility for overseeing the Trial at such Site;

1.1.10 ensure that the Investigational Product supplied pursuant to Glenmark's obligations hereunder is not used for any purpose other than the Trial;

1.2 Prior to the commencement of the Trial, the Investigator shall:

1.2.1 having regard to the scope of the Trial, eligibility criteria for Subjects, the Protocol and such relevant investigator, select and prepare a list of suitable Sites and the Co-Investigators (subject to section 1.1.9 above) for the Trial based upon the Investigator's assessment made at such time, evaluation of the patient database at such Site as well as ensuring that such Site has the necessary manpower, facilities and infrastructure to conduct the Trial pursuant to ICH-GCP guidelines and Glenmark's requirements and to collect and retain all essential documents including Consent Forms and the Trial Materials for each Site;

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GLENMARK LIFE SCIENCES LTD. ★ GLENMARK 400099.

1.2.2 compile and prepare all documentation necessary for seeking Ethics Committee's approvals for conducting such Trial;

1.2.3 obtain all appropriate approvals and authorisations and make all necessary arrangements for:

1.2.3.1 initiation, continuation and performance of the Trial in all selected Sites;

1.2.3.2 storage and administration of the Investigational Products at every Site for use in the Trial and of any other Trial Materials as well as storage, processing of laboratory samples and data taken from Subjects in the Trial;

1.2.3.3 obtain the necessary approvals from the Ethics Committee at each Site for the conduct of the Trial and storage and use of the Investigational Product;

1.2.3.4 prepare all necessary documentation for the performance of the Trial including language translations of Consent Forms and patient diaries into local languages;

1.2.4 educate and train all Site personnel involved, directly or indirectly, in the conduct of the Trial at each Site regarding ICH GCP guidelines and in relation to creating and maintaining the necessary documentation required during conducting the Trial including the management and compilation of the Site File;

1.3 In preparation for and during the conduct and performance of the Trial, the Investigator shall:

1.3.1 at each Site ensure that the Trial is performed specifically in accordance with the Protocol and the obligations hereunder;

1.3.2 at each Site ensure that the Co-Investigator is monitoring the conduct of the Trial at the Site and has completed all CRFs throughout the performance of the Trial;

1.3.3 ensure that Site has adequate and appropriate processes established and operating to ensure:

1.3.3.1 patient randomisation in pursuance with the Protocol;

1.3.3.2 maintenance of all study related logs regarding screening of the Subjects and their enrolment including proper collection and storage of all Consent Forms;

1.3.3.3 proper accounting and storage of Investigational Product and Trial Materials whilst on Site;

1.3.3.4 all other relevant and applicable communications and information regarding the Subjects and the Trial are recorded and logged, including telephone logs of clinical questions, CRFs and questions relating to CRFs;

1.3.3.5 ensure the expiry date, shelf life or use by date (or equivalent) of any Trial Materials or Investigational Product are monitored to ensure efficient rotation of stocks and safe destruction (pursuant to Glenmark's instructions) or return to supplier of any such materials that have expired;

[redacted]

1.3.3.7.2 ensuring any Ineligible Subject is not enrolled or participate in the Trial;

1.3.3.8 ensure randomisation of Subjects in the agreed timeframe and ensure adequate process for scheduling Subject visits as specified in the Protocol to ensure the Trial is in compliance with the Protocol;

1.3.3.9 conduct a close out visit at the Site on termination or expiry of the Trial or this Agreement as the case may be, during which any Trial Material, unused Investigational Product or any other material exclusively procured for the Trial purposes shall be collected and submitted to Glenmark or to the Central Storage Facility or by the Co-Investigators at the Sites pursuant to the written guidelines of Glenmark;

1.3.4 The Institution and the Investigator will provide all necessary support to Glenmark in fulfilling its obligations relating to the Trial including all support and expertise required for Adverse Event and SAE follow-up, tracking and reporting to applicable Agencies, Institutions and Sites, and providing status reports to the applicable Agencies.

1.3.5 The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct an audit at such intervals as required by Glenmark of all Services provided by the Investigator under this Agreement including all records and documents relating to the Protocol, Services and Trial, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and will provide such assistance as reasonably requested by Glenmark in connection therewith and shall ensure that Glenmark can audit the Site and the records of the Institution of such Site (including the Investigator's records) applicable to the Trial and Services.

1.3.6 The Institution and the Investigator will promptly notify Glenmark if the Co-Investigator ceases to be employed or engaged in the performance of the Trial at a Site together with the reasons why such the Co-Investigator is no longer involved and the Investigator will use best efforts to find a replacement acceptable to Glenmark as soon as possible.

1.4 The Institution and the Investigator warrant and represent that in entering into this Agreement it has not committed, any of the following acts:

1.4.1 providing or offering to provide to any person in the employment of the Institution and/or Site any gift or consideration other than that which is a reasonable financial arrangement either under this Agreement or by any other arrangement;

1.4.2 making payment or agreeing to make payment of any commission to any person in the employment of the Institution;

1.5 Institution and the Investigator will comply with all applicable laws and regulations in its/his/her performance of activities under this Agreement. Institution and Investigator will provide reasonable assistance to Glenmark so that Glenmark may comply with any applicable law or regulation in the performance of the activities under this Agreement.

1.6 Without limiting the generality of Section 1.5, Investigator will:

1.6.1 Take appropriate actions so that he/she will properly disclose protected or sensitive health information created or received by Investigator to Glenmark pursuant to any applicable Privacy Rule. Glenmark agrees to take appropriate measures to protect the privacy and confidentiality of the protected health information received in connection with the Trial.

1.6.2 Obtain a Glenmark approved written informed Consent Form from each Trial subject and will maintain a signed original of the written informed Consent Form in the Study subject's records.

2. <u>Glenmark Responsibilities:</u>

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2.1 Glenmark agrees and acknowledges that it will ensure that the Investigational Product supplied for the Trial is manufactured and supplied to the Sites as per the Protocol and that it complies with the obligations of a clinical Trial sponsor as delegated under this Agreement in accordance with section 5 of ICH GCP.

2.1.1 Prior to commencement of the Trial, Glenmark shall:

2.1.1.1 prepare and finalize the Protocol, patient information sheet and Consent Form in English, Investigator brochure and provide the Trial Material to the Investigator for compiling the submissions for Ethics Committee approvals;

2.1.1.2 develop and finalise the monitoring and source data verification plan ("Monitoring and SDV Plan");

2.1.2 During the course of the Trials, Glenmark shall:

2.1.2.1 appoint a physician to act as a medical monitor to respond to Site questions regarding Subjects, their eligibility, dose modifications of the Investigational Product and to develop, authorise and maintain Protocol exceptions and/or deviations;

2.1.2.2 review Adverse Events and SAE reports as received from the Sites, along with the drug safety contact of the Investigator who will be primarily responsible for Adverse Event and SAE management;

2.1.2.3 establish and maintain the safety database for each Site;

2.1.2.4 notify all Sites, the Co-Investigators and Agencies of reported Adverse Events and SAEs as required by statutory bodies;

2.1.2.5 prepare periodic status reports for the study for the Agencies;

2.2 Glenmark shall assist the Institution and the Investigator in the performance of Services relating to seeking and obtaining approvals from the Ethics Committee, providing and maintaining on-site specific training/support to the Investigator to enable it to provide appropriate training and support to each Site and archiving of Trial related documents.

RESPONBILITIES OF ALL PARTIES:

1. All Parties further understand, acknowledge and agree that prior to or at any time during the course of the Agreement, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

1.1. the Institution and the Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

1.2. All Parties will negotiate in good faith any amendments to modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

ANNEXURE 3
Standards

The following Standards are applicable to the provision of the Services by the Service Provider and Glenmark under this Agreement:-

- The Protocol annexed hereto as **Annexure 1** and any subsequent amendments
- ICH GCP
- Schedule Y (If an Indian study only)
- Other local laws and regulations

ANNEXURE 4

FPI and CRF completion timelines

First Patient in (FPI)	Jul 2017
FPI to last Patient in (LPI)	Jul 2017 – Jan 2018
LPI to Last Patient Out (LPO)	Jan 2018 – Jul 2018

- CRF to be completed within 3 days of patient visit.
- All DCFs should be resolved within 2 days of issuance.
- All SAEs reporting to Glenmark, Ethics Committee and Regulatory Authorities to be done as per local regulatory requirements.
- All safety reports/updates from other sites provided by Glenmark to the Site shall be submitted by the Investigator to the Ethics Committee within 7 days of the receipt of the same or within such period as may be statutorily laid down.
- In case of no recruitment within 30 days of Site Initiation a joint decision would be taken by Sponsor and Investigators for continuation in the study

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Site Budget	
Visit Details	Cost
Visit 1 (Screening & Lead-In)	5800
Visit 2 (Baseline-Day 1)	5500
Visit 3 (Day 8)	3900
Visit 4 (Day 29)	4200
Visit 5 (Day 57)	4200
Visit 6 (Day 85)	4400
Visit 7 (Day 112)	4200
Visit 8 (Day 141)	4200
Visit 9 (Day 169)	4600
Visit 10 (Day 183)	4000
Total Per Patient	**INR 45000**
Intitutional Overhead (20%)	**INR 9000**
Travel Reimbursements per patient all visit (1000/per visit x 10 visits	**INR 10000**

Description of Payments	**Cost(INR)**	**No. of patients projected at site**	**Total**
Total Per Patient	45000	30	13,50,000
Institutional Overhead Charges(20%)	9,000	30	27,0000
Travel Reimbursements per patient all visits	10,000	30	300,000
Site Facility Charges:- ECG(300x5)	1,500	30	45,000
Serum bicarbonate test 500X10	5,000	30	150,000
Serum Lactic acid test 1500X10	15,000	30	450,000
			INR 2,565,000

1. Patient travel reimbursement is upto maximum INR 1,000/- per visit and as per actuals. The amount for patient travel reimbursement mentioned above would be paid on actuals based on invoice received.
2. Local Laboratory and local test charges would be paid as per actual on case to case basis after confirmation from Sponsor.
3. Serum bicarbonate and Serum lactic acid test will be performed at local laboratory.
4. Payment for the recommended rescue medications (after confirmation from sponsor) would be paid on actuals, based on invoice received.
5. A maximum of 30% screen failed patients would be paid of the total randomized subjects an amount of Rs. 3000 as screening expenses only if screening procedures are conducted as per protocol at the end of the recruitment period.
6. As it is a competitive trial, the budget would be based on total number of patient enrolled on pro-rata basis for the grant mentioned above; for each completed patient.
7. For all patient visits, Investigator and Institute payments TDS will be deducted at source as per the existing rates.
8. Request for payment would be made by letter stating the amount on Investigator's

letter head/Institute letterhead and signed by Investigator/Hospital Authority after verified by the monitor per the completed visits and source data verified CRFs

9. The final payment would be released at the time of close out.
10. All payments made hereunder will be made in Indian Rupees.
11. Glenmark shall be entitled to deduct from any sums due hereunder any withholding taxes and other statutory duties which is mandatory to be deducted according to the applicable laws in force on the date of payment or invoice booking whichever is earlier.
12. GST (Goods and Service Tax) at the prevailing rate shall be payable by Glenmark in addition to the above Consideration.
13. All invoices shall mention the GST (Goods and Service Tax) number along with HSN code as mandated by law. If Grapecity Research solution LLP is exempted from GST, necessary certificates and declaration shall be provided by Grapecity Research solution LLP to Glenmark. If Grapecity Research solution LLP fails to comply with the above, then the invoice will not be payable by Glenmark.
14. Grapecity Research solution LLP shall pay all its GST liability & file its return on time to enable Glenmark to claim credit of the GST. If Grapecity Research solution LLP fails to comply with the same, then Sponsor will raise a debit note on Grapecity Research solution LLP for the default amount which Grapecity Research solution LLP will be liable to refund to Glenmark.
15. Any interest so charged by the authorities on Glenmark for default of Grapecity Research solution LLP, will also be recovered by Glenmark from Grapecity Research solution LLP by way of raising a debit note on Grapecity Research solution LLP.
16. If your site is given a laptop and/or dongle by Glenmark, then the same will be retrieved from your site before/during the Close Out Visit of your site.

Payee name	Grapecity Research solution LLP
PAN No.	AAPFG8186L
Name of the Bank and its Mailing address	ICICI Bank, plot No 1A , Gulmohar Road, aundh, Pune
Branch	Aundh
Bank Account No.	007305009846
IFSC code	ICIC0000073

ANNEXURE 6

Conditions Applicable to each the Co-Investigator

Each Co-Investigator:

1. must be free to participate in the clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

2. must not be involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Medicines Control Agency, the European Medicines Evaluation Agency, the General Medical Council or other regulatory Agencies. No data produced by the Co-Investigator in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

3. must have considered, and is satisfied that, facilities appropriate to the Trial are available to him at the Site and that he/she is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the performance of the Trial efficiently and in accordance with the obligations under the Agreement and Protocol.

4. must during the Trial, not serve as the Co-Investigator or other significant participant in any clinical Trial for another sponsor if such activity might adversely affect his/her ability to perform his/her obligations under this Agreement.

5. has not nor have his spouse nor any dependent children, entered into and will not enter into any financial arrangements with Glenmark or the Investigator to hold financial interests in Glenmark or the Investigator that are required to be disclosed pursuant to the US Code of Federal Regulations Title 21, Part 54, namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Trial could be influenced by the outcome of the Trial (as defined in 21 CFR 54.2(a)), (ii) any proprietary interest in the product being tested (as defined in 21 CFR 54.2(c)), (iii) any significant equity interest in Glenmark or the Investigator (as defined in 21 CFR 54.2(b)) and (iv) any significant payments from Glenmark or the Investigator such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria (as defined in 21 CFR 54.2(f)). In the case of subparagraphs (iii) and (iv) the Co-Investigator understands that such prohibitions relate to the period that the Co-Investigator is carrying out the Trial and for 1 year following completion of the Trial.

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Government of Karnataka

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Certificate No.	:	IN-KA03262010744535P
Certificate Issued Date	:	18-Mar-2017 11:29 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ COX TOWN/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0855290968587626P
Purchased by	:	BIOQUEST SOLUTIONS PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Dr HEMANGI RAJIV JERAJANI
Second Party	:	BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Paid By	:	BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Sector 18, Navi Mumbai - 410209

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai-410 209

----------Please write or type below this line----------

OBSERVATIONAL STUDY SITE AGREEMENT

This Observational Study Site Agreement ("Agreement"), having an effective date of 18-Mar-2017 ("Effective Date"),
between
Dr. Hemangi Rajiv Jerajani, an individual, having an address at MGM Medical College & Hospital, Sector 18, Kamothe, Navi Mumbai-410209, will serve as the principal investigator ("herein after referred to as Principal Investigator"),

Confidential H.R.J

BioQuest Solutions Pvt. Ltd.
Bangalore

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

And

the institution at MGM Medical College & Hospital, located at Sector 18, Kamothe, Navi Mumbai-410209, ("herein after referred to as Institution")

(collectively, Principal Investigator and Institution, with its personnel, officers, board members, affiliates and agents, shall herein after be referred to as "SITE"),

And

BioQuest Solutions Pvt. ltd, with a principal place of business at #24, Wellington St, Richmond Town, Bengaluru, Karnataka 560025. (herein after referred to as the CRO)

CRO, Site, and Principal Investigator are each individually referred to herein as a "Party" and collectively referred to herein as the "Parties."

RECITALS

WHEREAS, by separate MSA dated_____, Dr. Reddy's Laboratories Limited (collectively, with its personnel, officers, board members, affiliates and agents, "SPONSOR"), with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, has engaged CRO, a contract research organization, acting as an independent contractor, to act on behalf of SPONSOR for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiation and execution of the Agreement and payment administration of grant amounts in coordination with the SPONSOR and;

WHEREAS, CRO, acting as an independent contractor on behalf of SPONSOR, desires to coordinate an observational study entitled "**Real world, Non-interventional, Observational Study of Venusia® Max Cream as Moisturizer in Psoriasis**" ("the Study"), which shall be conducted according to SPONSOR's Protocol Number GGI-VENUSIA -11-16 ("Protocol") incorporated herein by this reference; and

WHEREAS, SPONSOR has developed an investigational product candidate designated as Venusia Max ("Investigational Product"); and

WHEREAS, SITE has acquired expertise in conducting research evaluations including observational studies; and

WHEREAS, SPONSOR and CRO wish to engage the SITE to facilitate and carry out the Study; and

WHEREAS, SITE has sufficient authority, competence and experience in conducting observational studies and, having reviewed the Protocol, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement; and

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BioQuest Solutions PVT. Ltd. Bangalore

WHEREAS, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth.

NOW THEREFORE THIS AGREEMENT WITNESSETH, that in consideration of the mutual covenants herein contained and other good and valuable consideration exchanged between the Parties, the receipt and sufficiency whereof is hereby acknowledged by the Parties hereto, the parties covenant and agree as follows:

ARTICLE 1

Statement of Work

1.1 SITE will take appropriate direction and supervision from CRO in connection with monitoring, supervision, and carrying out of the Study.

ARTICLE 2

Period of Performance

2.1 The performance of this Agreement shall be from the Effective Date till the date of termination of the Study by SPONSOR, unless earlier terminated in accordance with Article 12 of this Agreement.

ARTICLE 3

Conduct of the Study

3.1 The SITE agrees to conduct the Study in strict accordance with the Protocol attached to this Agreement as Attachment B, as amended from time to time, in accordance with the terms and conditions of this Agreement, and all applicable local laws and regulations applicable to the territory in which the Study is being conducted which is [mention the territory in which the Study is conducted] (herein after collectively referred to as, "Applicable Law").

3.2 The Study will be supervised by the Principal Investigator, who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the SITE, which the Principal Investigator and Institution represent and warrant are not inconsistent with (1) the terms of this Agreement, (2) the Protocol, (3) generally accepted standards of good clinical practice, and (4) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (1) – (4) of this Article 3.2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the

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Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the Principal Investigator and otherwise adhere strictly to the Protocol.

3.3 SITE will notify CRO immediately if Principal Investigator is unable to continue as principal investigator for the Study. Institution further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of CRO. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to CRO/SPONSOR is not available, this Agreement shall be terminated as provided for in Article 12.2.

3.4 As required by Applicable Law, prior to initiation of the Study, SITE shall ensure that the Protocol has been reviewed and approved by the appropriate Ethics Committee ("EC") and shall provide CRO with evidence of such EC approval pertaining to the: (i) the Protocol and/or any subsequent modifications thereof, and (ii) the informed consent form and/or any subsequent modifications thereof.

3.5 As required by Applicable Law, SITE shall obtain the informed consent of patients to participate in the Study prior to said participation, and shall document the Study patients' informed consent by securing from each patient, his or her signature upon an informed consent form that complies with Applicable Law and is approved by an appropriate Ethics Committee ("EC"), a copy of which shall be retained by the SITE. The Study patient shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.

3.6 SITE shall ensure that Study patients have agreed to participate in the Study as defined by the Protocol to be conducted at the Institution's facilities in compliance with Applicable Law.

3.7 SITE shall undertake to ensure that all Study patients are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, CRO, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study.

3.8 Institution and Principal Investigator hereby represents that neither: (a) has a conflict of interest that would affect the conduct of the Study; (b) has received any offer by SPONSOR, CRO and/or their respective representatives or affiliates, of any extra benefit for participation in the Study, including offers to family members. Further, SITE agrees to promptly notify CRO if it becomes aware of any conflict of interest that arises during the term of this Agreement. SITE not enter into any financial security transaction based on the Study data or the Study results. Without limiting the foregoing, SITE acknowledges that as of the date of this Agreement, neither Institution nor Principal Investigator are parties to any oral or written

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contract or understanding with any third party which (i) is inconsistent with this Agreement nor SITE's performance hereunder or (ii) will in any way limit or conflict with SITE's ability to fulfill its obligations under the terms of this Agreement. SITE further represents that it will not knowingly enter and will instruct its sub-investigators not to knowingly enter into any such conflicting agreements during the term of this Agreement

3.9 Adverse Events. SITE shall report to CRO and EC with a copy to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than twenty-four (24) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events.

3.10 No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and/or CRO and the SITE, and reviewed and approved by the EC in accordance with Applicable Law. If any changes in the Protocol affect the charge for research conducted in the Study, the SITE shall submit a written estimate of the charges for CRO's and SPONSOR'S prior written approval.

ARTICLE 4

Payment

4.1 In consideration of the work performed by SITE, payments shall be made to the SITE by CRO for evaluable Study patients in accordance with the terms of Attachments A; subject however, to the following terms and conditions:

4.1.1 In the event of early Study termination by SPONSOR, CRO, or the EC, as contemplated under Section 12 herein, the Institution will be reimbursed in full for completed Study patients except that Institution shall not be reimbursed in full or in part for any breach of this Agreement under Section 12.CRO shall reimburse Institution on a prorated basis for enrolled Study Subjects that are terminated early due to Sponsor, CRO, or EC termination of the Study. CRO will compensate Institution for services provided up to the effective date of termination and for any services provided after termination that are necessary to safeguard subject safety or comply with Applicable Law, rules, regulations or CRO requirements.

4.1.2 CRO reserves the right to temporarily withhold payment to Institution if it is determined from a monitoring visit or audit that there are significant errors in the Case record forms (CRFs) or where CRF's were not completed and/or provided to CRO in a timely manner.

ARTICLE 5

Record Keeping and Access

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5.1 Institution and Principal Investigator shall prepare, maintain and retain complete, current, organized, and legible Study documents relating to the performance of the Study which are required to be retained under Applicable Law and the Protocol (collectively, "Study Records") for each Study patient no later than ten (10) days after a visit. SITE shall respond to all data queries within seven (7) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords.

5.2 Authorized representative(s) of CRO and SPONSOR, after arranging in advance with the Principal Investigator and the SITE, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. Audits shall be at no additional cost to CRO/SPONSOR provided such audits are at mutually agreed intervals and do not significantly alter Institution's ability to meet any deadlines delineated in this Agreement.

5.3 Subject to ownership of intellectual property under Article 8 and SITE's right to publish under Article 6, all results, data, reports, documents, information and the like generated in connection with the Study shall be the property of SPONSOR and shall be delivered promptly to SPONSOR. After the required retention period under applicable law for the Study, SPONSOR will have the option (i) to have the records returned to Sponsor, (ii) to have the records destroyed, or (iii) to continue having the documentation stored as set forth herein (at no additional cost).

5.4 Regulatory Inspections and Audits.

A governmental or regulatory authority (including but not limited to representatives of the FDA or other international health agency or regulatory body, having similar regulatory authority over the subject matter of the Study) may, at reasonable times, examine and inspect the facilities being used to conduct the Study. In the event SITE is notified of any such regulatory inspection of SITE's records, facilities, equipment, or procedures, or other materials (including CRFs and patient medical records to the extent allowed by the informed consent document or other legal disclosure authorization), or request for access to the Principal Investigator and/or any sub-investigators to discuss the Study, SITE shall promptly notify CRO and shall provide CRO with copies of any reports issued by any such regulatory authority, and allow CRO to review and comment on any SITE response to such authority. If Institution is found deficient in any manner and reasonable efforts to correct the deficiency are ineffectual, CRO, in its sole discretion, shall either terminate SITE's continued participation in the Study and/or take such corrective actions as may be agreed between SPONSOR and CRO. It is further agreed that if Institution is notified that the Study is to be the subject of an audit, SITE shall promptly inform CRO and SPONSOR. If a formal response to any audit is required, Institution agrees to permit representatives of SPONSOR to review and comment on such response.

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ARTICLE 6

Publications

6.1 Neither Institution nor the Principal Investigator shall register the Study or Study results on any publicly accessible forum. Institution and Principal Investigator hereby acknowledge and agrees that the CRO/SPONSOR has the right to use the Study results in any manner deemed appropriate to CRO's/SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.

6.2 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 7

Confidentiality and Use Restrictions

7.1 CRO and/or SPONSOR will disclose to Principal Investigator and Institution, including its employees, agents, directors, and representatives, certain information furnished in any form, including written, verbal, visual, electronic or in any other media or manner, any information that a party would reasonably consider to be confidential or proprietary including, but not limited to, information concerning the Investigational Product, this Agreement, the Protocol, Study results, processes, know-how, discoveries, inventions, compilations, business or technical information, other materials prepared by either Party or their respective affiliates and representatives, containing or based in whole or in part, on any information furnished by the CRO and/or SPONSOR, and the procedures for carrying out the Study, (collectively, "Confidential Information"). SITE will keep, such Confidential Information in confidence and shall not use it for the benefit of nor disclose it to others, except as required by the Study or as defined in the Protocol and will at all times, refrain from any other acts or omissions that would reduce the value of CRO's/SPONSOR's Confidential Information. SITE agrees to ensure that its employees, agents, contractors, representatives, or affiliates (including members of the Study team), who have access to Confidential Information are bound by an obligation of non-disclosure and shall procure non-disclosure agreements with such parties with the same breadth of coverage as provided for in this Section 7. SITE's obligations of confidentiality shall not apply to that part of the Confidential Information that SITE is able to demonstrate by documentary evidence: (i) already in the public domain prior to receipt of such information by SITE, or (ii) that becomes lawfully part of the public domain through no act on the part of the SITE, and/or its employees, agents, and representatives; or (iii) is obtained from a third party without an express obligation of confidence; or (iv) where required by applicable law, regulation, legal process, or other applicable judicial or governmental order to disclose, provided that, should the SITE be required to make such disclosure, where legally permissible, SITE shall provide the SPONSOR and CRO with prompt written notice of such request or requirement so that SPONSOR and CRO may, at its sole expense, seek an appropriate protective order prior to such disclosure; and where SITE is compelled to disclose, SITE shall only disclose that portion of the Confidential Information that SITE is compelled to disclose and will exercise

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reasonable efforts to obtain assurance that confidential treatment will be accorded to that portion of the Confidential Information disclosed; or (v) is approved by CRO/SPONSOR with written authorization for disclosure by the SITE.

7.2 SITE shall return, retain or destroy all Confidential Information to CRO/SPONSOR at their request, at no additional cost, and under all circumstances except where retention of same is required by Applicable Law.

ARTICLE 8

Intellectual Property (IP)

8.1 For the purpose of this Agreement the term "Intellectual Property" or "IP" shall means all patents, trademarks, designs (whether or not registered) and applications therefor, present and future copyright, trade secrets, rights in know-how and other rights of confidence and all other rights of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world. Intellectual Property that either party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither party has any claims to, or rights in such intellectual property of the other party.

8.2 The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all Intellectual Property and Confidential Information provided to Institution and/or Principal Investigator relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Section 8.3 herein), Study data, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, "SPONSOR IP"). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The parties further agree that neither party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of Institution and Principal Investigator to use such information for: (i) Institution's own internal, non-commercial research and for

educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (ii) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

8.3 Without SPONSOR's prior written approval, SITE will not knowingly use in the Study, any of its own or any third-party intellectual property that may interfere with SPONSOR's rights to any SPONSOR IP and/or Study Invention. Except as stated elsewhere in the Agreement, the Parties expressly authorize the use and grant a royalty-free license to their respective intellectual property to the other Party and to SPONSOR, to the extent necessary to accomplish the purposes of the Study.

8.4 The SITE will not transfer the Investigational Product or related information to any third party, or otherwise make the Investigational Product or related information available to any investigator other than those listed in the SPONSOR'S Protocol, nor to any clinic or medical facility for use with patients not properly enrolled in the investigational Study, and hereby acknowledges that the SITE shall not use or exploit the results of the Study for any purpose other than that contemplated by this Agreement.

8.5 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 9

Use of Names

9.1 Neither party shall be permitted to use the name, trademark, trade name, logo, or any adaptation thereof, of the Sponsor and/or either Party hereto, in any news or publicity release, policy recommendation, advertisement, promotional material, promotional activity, or in any other commercial fashion, without the prior written consent of the other Party or where applicable, of SPONSOR subject, however, to the following:

9.1.1. CRO/Sponsor may, without prior consent, identify Institution and Principal Investigator as the entity and/or persons conducting the Study;

9.1.2. CRO/SPONSOR may disclose the name of the Institution and the Principal Investigator to investors or potential investors or as required by local laws or security exchange regulations.

9.1.3. SITE may, without prior consent, disclose their participation in the Study (but only with respect to the indication, treatment period) and may disclose SPONSOR as the source of funding for the Study as well as the Protocol title as necessary to comply with regulatory, academic, and governmental reporting requirements. SITE will not issue and will ensure the Study staff will not issue, any information or statement to the press or public, including but not limited to advertisements for the enrolment of Study patients, without, where appropriate, the review and prior written consent of the CRO and/or SPONSOR.

9.2. Nothing in this Article 9 shall be construed as prohibiting CRO/SPONSOR from submitting reports with respect to the Study to a governmental agency as required by law.

ARTICLE 10

Data Protection and Privacy

10.1 SITE shall undertake to ensure:
10.1.1 that data obtained from the Study patients in connection with the Study is utilized for no purposes other than as outlined in the Protocol and that SITE shall cause such data to be managed in accordance with Applicable Law;

10.1.2 compliance with Applicable Law on the protection of individuals with regard to the processing and free movement of personal data;

10.1.3 that all Study patients are properly informed that the data collected from them may be considered personal data and to obtain from such Study patients written consent to the processing, disclosure, and transfer of this data by SITE, CRO, and SPONSOR;

10.1.4 to provide information as requested by SPONSOR and CRO, to authorize the processing and storage of certain personal identifying information and data concerning a Study patient and/or SITE, and other site personnel involved in the Study for the purpose of fulfilling legitimate business requirements relating to the Study, meeting regulatory requirements, as well as for the purpose of evaluating SITE for inclusion in future studies; and

10.1.5 to obtain the consent of Study team members and all other personnel involved in the Study for the processing of their personal data as required by Applicable Law.

ARTICLE 11

Debarment

11.1 Principal Investigator and Institution hereby certify that they have not been debarred under (a) Applicable Law and (b) or excluded from participation in any government health care program. In the event that during the term of this Agreement, Principal Investigator or Institution (i) becomes debarred or excluded or (ii) receives notice of an action or threat of an

action with respect to its debarment or exclusion, SITE shall notify SPONSOR and CRO immediately.

11.2 In the event that SITE becomes aware of the debarment/exclusion or threatened debarment/exclusion of any individual, corporation, partnership or association providing services to SITE which directly or indirectly relate to activities under this Agreement, SITE shall notify SPONSOR and CRO immediately. Upon the receipt of such notice by SPONSOR or CRO, or if SPONSOR or CRO otherwise becomes aware of such debarment/exclusion or threatened debarment/exclusion, the provisions of Section 12.2 shall apply.

ARTICLE 12

Termination

12.1 Performance under this Agreement may be terminated by SPONSOR or CRO for any reason or no reason upon thirty (30) days written notice to SITE. Performance may be terminated upon thirty (30) days prior written notice by the SITE if circumstances beyond its control preclude continuation of the Study. However, termination of this Agreement shall not relieve SITE of its obligations under Articles 5, 6, 7, 8 and 9 of this Agreement or any other obligation which is specifically expressed to survive expiry or termination. Other than in cases of termination for breach of this Agreement by SITE, CRO on behalf of SPONSOR shall make all payments due hereunder to SITE for actual costs, non-cancellable commitments incurred in the performance of the research, which have accrued up to the date of such termination, or, in case of a termination of this Agreement pursuant to Section 12.2 (f), up to the date of receipt of such final rejection. Should Institution have received higher payments than the payments due according to the work already performed, Institution shall reimburse the balance to CRO.

12.2 Performance under this Agreement may be terminated by SPONSOR or CRO immediately upon written notice without any further action or notice by either party, in the event (a) SITE ceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct by SITE or its employees, contractors or agents which impacts or reasonably may impact the Study; (c) SITE's breach of this Agreement, or obligation and/or warranty hereof; (d) for reasons related to Study patient safety as determined by SPONSOR and/or CRO; (e) the Principal Investigator ceases or is unable to serve and a successor acceptable to SPONSOR or CRO cannot assume his/her duties within a reasonable period of time; (f) in case any regulatory or legal authorization necessary for the conduct of the Study is finally rejected; (g) in the event that Principal Investigator or Institution becomes debarred, threatened with debarment or any similar proceeding, is excluded from being able to participate in any such Study, and/or utilizes the services of a third party directly or indirectly in order to perform obligations related to the activities under this Agreement that has been debarred, threatened with debarment or any similar like proceeding.

12.3 Except as otherwise provided above, where either party fails to perform any of its material non-monetary obligations under this Agreement, and does not cure such breach within thirty (30) days of receipt of written notice of such default, then the non-defaulting party, at its option, may terminate this Agreement by giving written notice of termination to the defaulting party. In such event, this Agreement shall terminate on the date specified in such notice.

12.4 Upon completion, termination (early or otherwise), suspension or discontinuation of the Study or upon the request of CRO, Institution and Principal Investigator will immediately cease Study activities and complete its normal Study completion responsibilities in an orderly and safe manner, of which shall include but is not limited to:(i) cooperate promptly and diligently in an orderly and safe manner, in the wind down of the Study, allowing SPONSOR and/or CRO access to records and facilities for Study close-out procedures, requiring Investigator to complete any actions required by the role of Investigator, and transferring to CRO all Study data and, if applicable, the administration and conduct of the Study; (ii) allowing Sponsor and/or CRO access to records and facilities for Study close-out procedures, and requiring Investigator to complete any actions required by the role of Investigator; and (iii) Immediately delivering to the CRO and/or SPONSOR, all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes.

ARTICLE 13

Liability/Indemnification/Insurance

13.1 CRO. CRO shall be liable for and agrees to indemnify and hold Institution harmless from and against, any and all any/all claims, damages, liabilities and losses (including reasonable attorney's fees and expenses) (collectively, "Losses") arising out of CRO's negligent act, omission or wilful misconduct.

13.2 Institution. Institution shall be liable for, and agrees to indemnify and hold the CRO and Sponsor harmless from and against, any and all Losses caused by or attributable to Institution's (including Investigator), and/or any of its affiliates, subsidiaries, employees (including sub-investigators), officers, directors, contractors, sub-contractors, consultants or agents (collectively, "Representative(s)"): (i) negligent acts, omissions, wilful or intentional and/or professional malfeasance or misconduct of any Representative(s) involved in the Study; and (ii) breach of any of the terms of this Agreement or for violation of Applicable Law.

EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTIONS 13.1 AND 13.2 OR OTHERWISE SEPARRATELY AGREED IN WRITING, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST PROFITS, WHETHER OR NOT A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE.

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13.3 Insurance

Institution represents that it will maintain general and professional liability insurance and if applicable, workers compensation insurance, covering Institution's liability and the liability of its employees (including, Investigator and sub-investigator(s)) and its trustees, officers, agents, or directors, in amounts sufficient to adequately cover its obligations hereunder. Institution shall maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two (2) years thereafter. Institution will provide evidence of all such coverage upon request. Institution will notify CRO within twenty (20) days of any notice of cancellation, non-renewal, or material change in its insurance coverage.

13.4 The obligations described in this Section 13 shall survive the expiration or termination of the Agreement.

ARTICLE 14

Miscellaneous

14.1 Assignment and Succession

This Agreement and the rights and obligations hereunder granted to and undertaken by CRO may be assigned by CRO and/or SPONSOR without prior written approval of SITE. Neither this Agreement, the obligations hereunder nor the rights granted to the SITE under this Agreement shall be assignable or otherwise transferable by the SITE without the prior written consent of CRO. Any such assignee of the SITE shall be bound by the terms hereof as if such assignee were the original party hereto. Any assignment in violation of this provision shall be deemed null and void and of no effect.

14.2 Independent Contractor Status

In the performance of this Agreement the Principal Investigator and Institution shall be independent contractors with respect to CRO and SPONSOR. Neither Principal Investigator nor Institution is authorized to act as the agent for CRO or SPONSOR. CRO and SPONSOR shall not be bound by the acts of the Principal Investigator or Institution.

14.3 Notices

Any notices concerning the administration of this contract which are required or permitted by this contract shall be delivered by hand, sent by mail, or by facsimile to the following party:

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to INSTITUTION:

Institution Address:
MGM Medical College & Hospital
Sector 18, Kamothe, Navi Mumbai-410209

Attention: Dr. Hemangi Jerajani

Telephone:9820031483

To INSERT CRO NAME/ADDRESS:

BioQuest Solutions Pvt Ltd
#24, Wellington street, Richmond town
Bangalore - 560025

and to SPONSOR at:

Dr. Reddy's Laboratories, Limited
8-2-337, Road No. 3, Banjara Hills
Hyderabad, Telangana 500034 (INDIA)
Fax: +914049002999

or to such other addresses as specified by the Parties in writing.

14.4 Applicable Law

This Agreement shall be governed by the laws of India. Any proceeding arising out of or relating to this Agreement shall be brought in the courts located in Hyderabad. Each of the Parties irrevocably submits to the exclusive jurisdiction of such court in any such proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims with respect to this Agreement shall be heard and determined on in such court, and agrees not to bring any claim arising out of or relating to this Agreement in any other court.

14.5 Impossibility and Waiver

In the event that any further lawful performance of this Agreement or any part thereof by any party hereto shall be rendered impossible by or as a consequence of any law or administrative ruling of any government, or political sub-division thereof, having jurisdiction over such party, such party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

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14.6 Force Majeure

Any delays in or failure by either party in performance of any obligations hereunder shall be excused if and to the extent caused by such occurrences beyond such party's reasonable control, including but not limited to acts of God, strikes, or other labor disturbances, war, whether declared or not, sabotage, and other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the party who failed to perform.

14.7 Conflict between Agreement and Protocol

If the event provision of this Agreement conflicts with a provision of the Protocol relating to the conduct of the Study, the Protocol shall take precedence on matters of medicine, science and Study conduct. This Agreement takes precedence in any other conflicts.

14.8 Third Party Beneficiaries

Notwithstanding any other provision in this Agreement to the contrary, the Parties agree that the SPONSOR is an intended third-party beneficiary of this Agreement and shall have the full right to enforce any and all obligations owned to it as through it were a party to the Agreement.

14.9 Severability

The provisions of this Agreement shall be deemed severable. Therefore, if any part of this Agreement is rendered void, invalid or unenforceable; such rendering shall not affect the validity and enforceability of the remainder of this Agreement unless the part or parts which are void, invalid or unenforceable as aforesaid shall substantially impair the value of the whole agreement to either party.

14.10 Integration and Amendment

This Agreement sets forth the entire agreement between the parties and merges all prior communications relating to the subject matter contained herein and may not be modified, amended or discharged except as expressly stated in this Agreement or by a written agreement signed by the parties hereto.

14.11 Warranties

Principal Investigator and Institution, for itself and its officers and directors, warrant and represent that they: (a) possess the necessary resources, skills, expertise and training to complete the Protocol professionally and competently; (b) are familiar with current laws and regulations related to the Study, and maintain a program for regularly updating their familiarity and compliance with such laws and regulations; (c) are licensed and in good standing with all necessary and appropriate government agencies; (d) have never been disciplined or debarred by any government agency; (e) have never been convicted of a

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felony; (f) are not currently the subject of any regulatory, civil or criminal investigation; and (g) shall maintain and provide evidence upon request comprehensive general liability insurance, professional liability insurance and worker's compensation insurance.

14.13 Counterparts

This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Facsimile and PDF signatures shall be treated as original signatures.

14.14 Headings

Headings are used in this Agreement for convenience only and shall not affect any construction or interpretation of this Agreement.

IN WITNESS, WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

to INSTITUTION:

PRINCIPAL INVESTIGATOR

By: H.R. Jerajani

Printed Name: Dr. H.R. Jerajani

Title: Professor & HOD, Dept of Dermatology

Reg. No. MMC 37586

Professor and H.O.D.
Department of Skin and VD
MGM Medical College
Kamothe, Navi Mumbai

BioQuest Solutions Pvt. Ltd

By: _____

Printed Name: Gautam. V. Sathia

Title: MD & CEO.

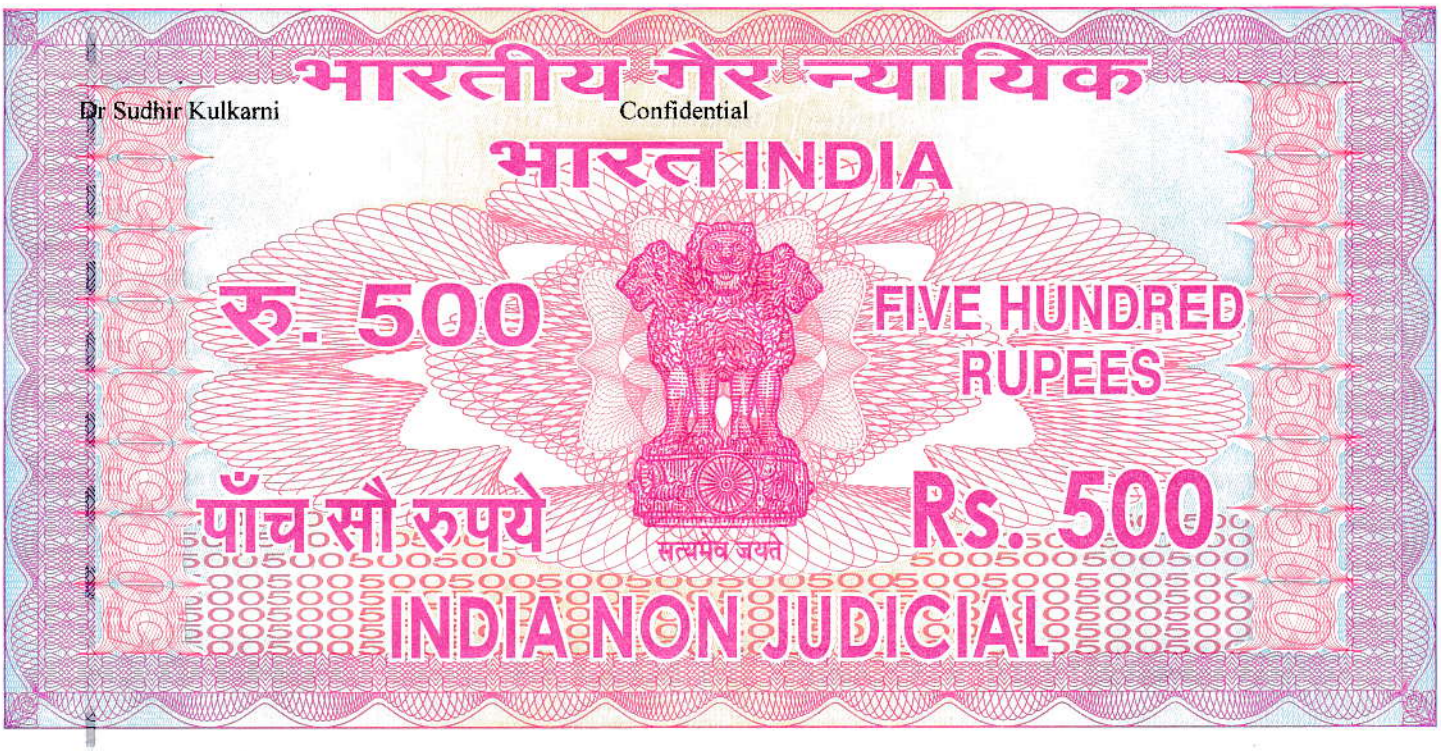
INSTITUTION

By: _____

Printed Name: Dr. G.S. Narshetty

Title: Dean

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209



महाराष्ट्र MAHARASHTRA ◐ 2016 ◐ AC 366625

मुद्रांक विक्री नोंदवही अनु. क्रमांक 2442 दिनांक 19 MAY 2017
दस्ताचा प्रकार- Consent Agreement मुद्रांक शुल्क रक्कम 500 = -
दस्त नोंदणी करणार आहेत का? होय(Yes)/ नाही(No)
मिळकतीचे थोडक्यात वर्णन-
मुद्रांक विकत घेणाऱ्याचे नांव Lupin Ltd - Nande Mulashi Pune
दुसऱ्या पक्षकारांचे नांव Dr. Sudhir Kulkarni - MGM IMCEC - Aurangabad.
हस्ते असल्यास त्यांचे नांव Parmod Kulkarni - Vidyanagar Pune

19 MAY 2017

रविंद्र वा. मिरजकर
ला. नं. HVL VIII-2201096
शिवाजीनगर, पुणे- 32.
मुद्रांक विकत घेणारे/ हस्ते व्यक्तिची सही

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

CLINICAL TRIAL AGREEMENT
Protocol # LRP/LNP1892/2016/007

This Clinical Trial Agreement ("Agreement") is made as on 14th August, 2017 between

Lupin Limited, incorporated under the laws of India with its registered office located at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz East, Mumbai 400055 and having PAN: AAACL1069K, including its successors, assigns and Affiliates (hereinafter "**Lupin**");

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

and

Dr Sudhir Kulkarni, an Indian citizen/ resident, with his address at Advet, 113, Samarth Kidney and Hypertension Clinic, Tilak Nagar, Aurangabad 431001 and having PAN: ABPPK6988B (hereinafter "**Principal Investigator**");

and

Mahatma Gandhi Mission Medical College and Hospital, with its address at N-6, CIDCO, Aurangabad 431003 (hereinafter "**Institution**")

and

Grapecity Research Solutions LLP, limited liability partnership having its registered address at Block No. D/2, Prakash Hsg. Society, Near Kalewadi Fata, Thergaon, Pune 411033 and having PAN: AAPFG8186L (hereinafter "**SMO**").

Lupin wishes to support a clinical trial entitled Protocol # LRP/LNP1892/2016/007 "A Randomized, Double – Blind, Placebo – Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis" ("**Protocol**") to be conducted at Institution and to involve Trial Subjects (collectively, "**Trial**" or "**Study**").

The parties agree as follows:

1. Definitions:

1.1 **Affiliate**: means with respect to a Person, any other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/ or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.2 **Applicable Laws**: means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, license, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.3 **Authority**: means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.4 **Intellectual Property Rights**: includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or forms of protection having equivalent or similar effect anywhere in the world and the term 'registered' includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.5 **Invention**: shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.6 **Party:** means Lupin, Institution, Principal Investigator and SMO and "Parties" shall mean all of them.

1.7 **Person**: means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.8 **Study Site:** means the premises on which the Study will be carried out.

1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11 **Regulatory Approval**: mean any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.12 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. Investigators and Research Staff.

2.1 Principal Investigator. The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 Sub-investigators and Research Staff. Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Trial as Sub-investigators or Research Staff.

2.3 Obligations of Principal Investigator. Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standards including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 No Substitution. Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Lupin. In the event Lupin approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Lupin does not approve a replacement principal investigator, Lupin will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 Delegation of duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Lupin promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. Protocol. The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 Amendments. The Protocol may be modified only by a written Amendment, signed by both, Lupin and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Institutional Ethics Committee ("IEC").

3.2 Emergency Amendments. If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Lupin and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Lupin and the Principal Investigator.

3.3 No Additional Research. Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Lupin in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. Institutional Ethics Committee. Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 Trial Disapproval. If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

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5. Trial Conduct. Principal Investigator will conduct the Trial in accordance with the Protocol, Lupin's or its designee's written instructions and Applicable Law.

5.1 Trial Initiation: Prior to initiation of the Trial, Lupin shall organize an investigator meeting for all investigators who are taking part in the clinical trial for Lupin Drug, at such place and time as finalized by Lupin ("**Investigator Meeting**"). The purpose of the Investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Lupin Drug. The Principal Investigator agrees to attend the said Investigator Meeting along with such members of its Research Staff, as approved by Lupin ("**Attendees**"). Lupin agrees that it shall arrange for the travel and boarding and lodging of the Investigator Meeting Attendees.

6. Lupin Drug. Lupin will provide the Principal Investigator with sufficient quantities of Lupin product that is being studied ("**Lupin Drug**") to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Lupin will also provide placebo or comparator drug ("**Comparator Drug**").

6.1 Custody and Dispensing. Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Lupin Drug or Comparator Drug, as well as appropriate documentation of such activities.

6.2 Control. Principal Investigator will maintain appropriate control of supplies of Lupin Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 Use. Principal Investigator will use Lupin Drug or Comparator Drug only as specified in the Protocol. Any other use of Lupin Drug or Comparator Drug constitutes a material breach of this Agreement.

6.4 Ownership of Lupin Drug. Lupin Drug is and remains the sole and exclusive property of Lupin. Lupin grants or assigns Principal Investigator no express or implied intellectual property rights in Lupin Drug or in any methods of making or using Lupin Drug.

6.5 Payment for Lupin Drug or Comparator Drug. Principal Investigator will not charge a Trial Subject or third-party payer for Lupin Drug or Comparator Drug or for any services reimbursed by Lupin under this Agreement.

7. **Representation and Warranties**:

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Lupin the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Lupin from time to time;

c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Lupin, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set out hereunder may be relied upon in any applications to any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Laws or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Lupin in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Lupin for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Lupin in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

n. The Principal Investigator and/or the Institution shall not in any during the course of its

business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the Agreement. Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonably required by Lupin from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Lupin hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Lupin, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Lupin, who shall claim such Intellectual Property Rights through Lupin and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Lupin, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Lupin.

8.3 Principal Investigator and the Institution hereby jointly undertake that:

a. The Principal Investigator will unequivocally transfer to Lupin the right to obtain patent on Invention.

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b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Lupin. To ensure the duties set forth in this Section are carried out, Lupin may, at its own cost, request that Principal Investigator prepares and signs appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Lupin. Lupin has the exclusive right to choose the form of protection of intellectual property.

c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Lupin in any way. Moreover, Principal Investigator agrees to inform Lupin of any known infringement of its Intellectual Property Rights, and to support Lupin, at Lupin's expense, in actions intended to protect Lupin's Intellectual Property Rights.

d. Lupin shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Lupin.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. Research Grant. Funding will be made to the SMO on behalf of the Principal Investigator, by way of grant payments in accordance with Attachment-B. The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties. The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Lupin, including, but not limited to, Lupin Drug, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Lupin Drug and/or Comparator Drug administration.

Principal Investigator and the Institution hereby agree that Lupin can make all payments to the SMO on their behalf and that the Principal Investigator and/or the Institution do not have any objection to the same.

It is the responsibility of the SMO, institution and the Principal Investigator to sort out any payment related disputes amongst themselves and Lupin shall not be responsible in any manner whatsoever for the same. The SMO, Principal Investigator and the Institution hereby jointly and severally indeminfy Lupin from any loss that Lupin may suffer as a result of such dispute affecting the Trial in any manner.

10. Trial Subject Enrollment. Principal Investigator has agreed to enroll Trial Subjects in the Trial in accordance with the Protocol. Lupin reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 Multi-Center Studies. Lupin may discontinue patient enrollment if the total enrollment needed for a multi-center Trial has been achieved.

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11. Informed Consent. Principal Investigator undertakes that it will obtain a written Informed Consent Form ("**ICF**") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Lupin an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Lupin or its designee to inspect signed ICFs or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Lupin for review and written approval by Lupin before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs an ICF approved by Lupin and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

12. Adverse Events. Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If a Trial Subject is physically injured by Lupin Drug or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Lupin, Lupin will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. Protected Health Information. The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting it from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 Authorization to Use and Disclose Health Information. Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Lupin and other persons and entities designated by Lupin with completed Case Report Forms ("**CRFs**"), source documents and all other information required by the Protocol. Lupin, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfill their assigned duties with respect to the Trial. Such use also will be restricted to those uses permitted in the authorization forms and neither Lupin nor any party to whom Lupin may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Lupin an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. Confidential Information. During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Lupin Affiliate.

14.1 Definition. Except as specified below, Confidential Information includes all information provided by Lupin, or developed for Lupin, Inventions (hereinafter defined), and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with Lupin, commercialization and Trial strategies, trade secrets and know-how disclosed by Lupin to Principal Investigator and/or the

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Institution directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

14.2 Exclusions. Confidential Information does not include information that is in the public domain prior to disclosure by Lupin; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

14.3 Obligations of Confidentiality. Unless Lupin provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

14.4 Disclosure Required by Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator and/or the Institution notifies Lupin or Lupin in writing as far as possible in advance of the disclosure so as to allow Lupin to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 Survival of Obligations. For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Data are described in Sections 18 (Publications) of this Agreement.

14.6 Return of Confidential Information. If requested by Lupin, Principal Investigator will return all Confidential Information, at Lupin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Trial Data, Biological Samples, and Records.

15.1 Trial Data. During the course of the Trial, Principal Investigator will collect and submit data to Lupin or its agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Lupin or its agent, such as X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. Ownership of Trial Data. Subject to Principal Investigator's right to publish, with prior written intimation to Lupin, the results of the Trial and the non-exclusive license that permits certain uses, Lupin is the exclusive owner of all Trial Data.

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b. Non-Exclusive License. Lupin grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. Medical Records. Medical records relating to Trial Subjects that are not submitted to Lupin may include some of the same information as is included in Trial Data; however, Lupin makes no claim of ownership to those documents or the information they contain.

d. Personal Information Protection. Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 Biological Samples. If so specified in the Protocol, Principal Investigator may collect and provide to Lupin or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. Use. Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Data. Lupin or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Lupin will not provide the results of such tests ("Sample Data") to the Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Lupin provides Sample Data to the Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

15.3 Records. Principal Investigator will ensure that Trial Subject's Trial records, which include the Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. Retention. Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Lupin authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Lupin's prior written permission to do so; provided, however, that if Lupin does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Lupin, then Principal Investigator may forward all such records to Lupin, at Lupin's expense, or continue to retain such records. Principal Investigator further agrees to permit Lupin to ensure that the records are retained for a longer period if necessary, at Lupin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage). \

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16. Inspections and Audits.

16.1 Access. Upon reasonable request by Lupin, authorized representatives of Lupin, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy: all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe the conduct of the Trial.

16.2 Notice. Principal Investigator and/or the Institution will inform Lupin within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Lupin with a copy of any communications sent by such persons; and will provide Lupin or Lupin the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 Cooperation. Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Lupin copies of any inspection findings that Principal Investigator receives from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Lupin with an opportunity to prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Lupin. Principal Investigator will assign all interest in any such Invention to Lupin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Lupin in filing and prosecuting any patent applications relating to Invention, at Lupin's expense.

18. Publications. Principal Investigator acknowledges that Lupin has the right to use the Study Results in any manner deemed appropriate to Lupin's business interests, both during, and following termination/expiry of, this Agreement. Lupin shall have the sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Lupin shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Lupin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial, Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. Publicity. Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Lupin reserves the right to identify the Principal Investigator in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

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20. Indemnification.

20.1 Lupin agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Lupin Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Lupin further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Principal Investigator further agrees to promptly notify Lupin in writing of any such medical injury.

a. Exclusions. Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Lupin (b) failure of an Indemnified Party to comply with any Applicable Law and governmental regulations, or (c) fraud, negligence or willful misconduct by an Indemnified Party.

b. Notice and Cooperation. Principal Investigator agrees to provide Lupin with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Lupin, Principal Investigator agrees to authorize Lupin to carry out the sole management of defense of an indemnified claim.

c. Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on Lupin without Lupin's prior written consent. Lupin will not unreasonably withhold such consent of a settlement or compromise. Neither party will admit fault on behalf of the other party without the written approval of that party.

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Lupin including its directors, employees, representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Lupin;
b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Lupin to redo the Study;
c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;
d. any negligent act or omission or willful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential or special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

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20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Lupin shall, in addition to any other right that Lupin may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Lupin the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Lupin may incur for repeating the Study. Further without prejudice to any other rights that Lupin may have under law or equity, Lupin may, at its discretion, forthwith terminate this Agreement.

21. Termination.

21.1 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. Disapproval by IEC. If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. Trial Completion. For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subjects; receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

c. Early Termination of Trial. If the Trial is terminated early as described below, the Agreement will terminate after receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either party.

(1) Termination of Trial Upon Notice. Lupin reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) Immediate Termination of Trial by Lupin. Lupin further reserves the right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Lupin notifying Principal Investigator of such breach; (ii) failure to enroll Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Lupin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Lupin Drug or Comparator Drug.

(3) Immediate Termination of Trial by Principal Investigator. Principal Investigator reserves the right to terminate the Trial immediately upon notification to Lupin or Lupin if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.2 Payment upon Termination. If the Trial is terminated early in accordance with this Agreement, Lupin will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with Attachment-B, less payments already made. The termination payment will include any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Lupin, and, only to the extent such costs cannot reasonably be mitigated. If the Trial was never

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initiated because of disapproval by the IEC, Lupin will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Lupin.

21.3 Return of Materials. Unless Lupin instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Lupin, at Lupin's expense, for Trial conduct, and any Lupin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Lupin, at Lupin's expense, unless otherwise specified by Lupin, any unused Lupin Drug or Comparator Drug.

22. Insurance. The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

23. Debarment, Exclusion, Licensure and Response. Principal Investigator and the Institution jointly and severally certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under Applicable Law with respect to services to be performed under this Agreement. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and the Institution will notify Lupin promptly in writing to the extent possible, within two (2) business days if either of these certifications needs to be amended in light of new information or if Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Lupin regarding any responsive action necessary.

24. Assignment and Delegation. Lupin may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Lupin or substitute Lupin with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Lupin, and the express agreement of Principal Investigator and/or the Institution, Lupin, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Lupin, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Lupin.

25. Equipment. Lupin may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

26. Survival of Obligations. Obligations relating to Research Grant, Confidential Information, Inventions, Records, Publications, Publicity, Debarment and Exclusion, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. Entire Agreement. This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. Conflict with Attachments. To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

29. Relationship of the Parties. The relationship of Principal Investigator and/or the Institution to Lupin is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. Force Majeure. Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. Governing Law. Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Mumbai.

32. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO LUPIN:
Attn. To: Dr Dhananjay Bakhle
Executive Vice President
Lupin Limited (Research Park)
Survey. No. 46A/47A, Village Nande,
Taluka Mulshi, Pune – 412115, Maharashtra, India

TO PRINCIPAL INVESTIGATOR:
Attn. To: Dr Sudhir Kulkarni
Mahatma Gandhi Mission Medical College and Hospital
N-6, CIDCO, Aurangabad – 431003,
Maharashtra, India

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

TO INSTITUTION:
Attn. To: Dr Rajendra Bohra
Mahatma Gandhi Mission Medical College and Hospital
N-6, CIDCO, Aurangabad – 431003,
Maharashtra, India

In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence a binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

ACCEPTED AND AGREED BY:

PRINCIPAL INVESTIGATOR

By:
Signature

Dr. Sudhir Kulkarni
Printed Name

principle investigator
Title

20 Aug 2017.
Date

ACCEPTED AND AGREED BY:

LUPIN LIMITED

LUPIN LIMITED MUMBAI

By:
Signature

DR. DHANANJAY BAKHLE
Printed Name

EXECUTIVE VICE PRESIDENT, MEDICAL RESEARCH
Title

14th Aug 2017
Date

ACCEPTED AND AGREED BY:

INSTITUTION

By:
Signature

Printed Name DR RAJENDRA BOHRA

Title DEAN

21 AUG 2017
Date

MGM's Medical College Aurangabad

ACCEPTED AND AGREED BY

SMO

By:
Signature

DR SUSHIL CHAUDHARY
Printed Name

DIRECTOR
Title

20/Aug/2017
Date

LUPIN OK LEGAL

MGM's Medical College Aurangabad

Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 15 December, 2016 and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol # LRP/LNP1892/2016/007 "A Randomized, Double – Blind, Placebo – Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis"

Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. General Terms. Principal Investigator ("Payee") will be paid the per patient grant amount as outlined on Attachment-D (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. Payment Terms. Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted. Invoices will be issued by Payee upon notice delivered by Lupin. Payments will be made in accordance with eCRFs submitted and monitored, and in accordance with Attachment D "Research Grant Worksheet". Monitoring will occur based on site enrollment and completion of data entry. Payments will be made in quarterly installments on a pro-rata basis. Undisputed invoices will be paid by Lupin within 60 (sixty) days of such invoice issue date.

B-3. Non-Procedural Costs. Payee will be paid for additional non-procedural costs that are pre-approved by Lupin, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Lupin or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Lupin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Lupin Drug is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial. Lupin or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any. Payee will promptly reimburse Lupin amounts overpaid within thirty (30) days of notification by Lupin or designee.

B-5. Taxes.

(1) All payments to Payee by Lupin will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") regime ("GST Law"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Lupin harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Lupin. The Payee shall fully co-operate with Lupin to respond to the relevant tax authorities' demands, and to resolve any mismatch of Lupin and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Lupin will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full

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responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

B-6. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. Patient travel reimbursement. Lupin, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Lupin approval. Any payment will be based on the invoice together with supporting documentation (i.e receipts) submitted to Lupin.

B-8. Administrative Start-up Fees. This is not applicable for this site.

B-9. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Lupin in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Lupin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Lupin will be notified as soon as practicable after the fact.

B-10. Payee. The research grant payments will be made to the following payee and address:

Payee Name: **Grapecity Research Solutions LLP**
Payee Address: **Block No. D/2, Prakash Hsg. Society, Near Kalewadi Fata, Thergaon, Pune – 411033, Maharashtra, India**
Payee GST Number: **AA270817044477Q**
Payee PAN No.: **AAPFG8186L**
Payee Bank Account Details: **Current Bank Account**
Bank Name: **ICICI Bank**
Bank Address: **Gulmohar Park, Plot no. 1 A ITI Road, Aundh Pune- 411007**
Bank Account Number: **007305009846**
IBAN Number: **NA**
IFSC Code: **ICIC0000073**
Email address for remittance information: **sushilrc.chaudhary@gmail.com**

In case of changes in the Payee's bank account details, Payee is obliged to inform Lupin in writing, but no amendment to this Agreement shall be required.

B-11. Invoices. All invoices must be issued and forwarded to the following as instructed:

Lupin Limited (Research Park),
Survey. No. 46A/47A,
Village Nande, Taluka Mulshi,
Pune – 412115, Maharashtra, India
Attn: Dr Rajesh Kumawat

Each invoice must contain: (1) Lupin name, (2) Protocol number, (3) Project code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (3) the

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GST Registration Number, (4) if GST reverse charge mechanism applies, the note "GST reverse charge applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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Attachment C

EQUIPMENT USE, OWNERSHIP & DISPOSITION

1. Use. During the term of this Agreement, Principal Investigator may use Equipment only for purposes of this Trial.

2. Ownership. Until the termination of this Agreement, this Equipment remains the property of the respective vendors that have provided the equipment to Lupin and must be returned either within a reasonable period of time upon request by Lupin, not to exceed five (5) calendar days, or immediately upon termination of this Agreement. Principal Investigator agrees to return the Equipment in the manner directed by Lupin in substantially the same condition as when received by Principal Investigator. Principal Investigator agrees to be financially responsible for obtaining insurance to cover any loss or destruction to Equipment while in Principal Investigator's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Trial. Principal Investigator further agrees that unless otherwise authorized in writing by Lupin of this Trial, Principal Investigator will not alter the Equipment in any way. Principal Investigator must not install any components or software, if applicable, without express approval of Lupin. Any software provided to Principal Investigator may not be duplicated. Principal Investigator is not permitted to use the Equipment for any other purpose than for the performance of this Trial in accordance with the Protocol. Lupin shall not have any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the negligence or willful misconduct of Lupin, as applicable, and except to the extent that a personal injury constitutes a compensable Trial Subject injury to be paid by Lupin as described in this Agreement.

3. Return to Lupin. After completion of Trial conduct or at an earlier time specified by Lupin, Principal Investigator will arrange for return of Equipment and Lupin materials, at Lupin's expense, to Lupin or a location designated by Lupin.

Attachment D

RESEARCH GRANT WORKSHEET

Grant Worksheet **Principal Investigator: Dr. Sudhir Kulkarni** **Protocol No.: LRP/LNP1892/2016/007**	
Main Study	
Investigator Grant Per Patient	***Cost (INR)***[1]
Screening (All activities per protocol)	9,000
Day 1 (All activities per protocol)	11,000
Day 8 (All activities per protocol)	4,000
Day 15 (All activities per protocol)	4,000
Day 30 (All activities per protocol)	11,000
Day 60 (All activities per protocol)	11,000
Day 90 (All activities per protocol)	11,000
Day 97 (All activities per protocol)	9,000
Total per patient amount - Main Study	**70,000**
PK PD Study	
Investigator Grant Per Patient	***Cost (INR)***[1]
Screening (All activities per protocol)	9,000
Day 1 (All activities per protocol)	6,000
Day 2 (All activities per protocol)	3,000
Day 8 / EOT (All activities per protocol)	6,000
Day 9 (All activities per protocol)	2,000
Day 10 (All activities per protocol)	2,000
Day 15 / FU Visit (All activities per protocol)	2,000
Total per patient amount - PK PD Study	**30,000**
TOTAL PER PATIENT GRANT AMOUNT (MAIN STUDY & PK PD STUDY)	**1, 00,000**

Additional Study Related Costs	***Cost (INR)***[1]
Screen Failures[2]	9,000
Patient travel reimbursement	500
12 Lead ECG (Only at Protocol scheduled time points)	500
Ultra-Sonography (USG) Neck (Only For Main study, Parathyroid Gland size assessment at protocol scheduled time points)	1,800
Hospital Per day charges (Night stay) (As per PK PD protocol schedule only)	2,800

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Hemodialysis cycle (Post randomization per cycle cost, Only for patients randomized on hemodialysis arm)	2,800
Institutional Overheads[3]	10%

Invoiced Charges[4]	*Cost in INR*[1]
Archival Fees (For 15 Years)	30,000
TOTAL Invoiced Charges	**30,000**

Notes:
[1]Total Costs are inclusive of indirect cost.
[2]Ratio: 1:1 (One (1) Screen Failure for every one (1) subject randomized into the Study. Screen Fails are
[3]Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.
[4]Invoiced Charges to be paid upon receipt of invoice from Principal Investigator, before site close out.

MGM's Medical College Aurangabad

LUPIN LIMITED MUMBAI

cliantha research limited

CP/04/12.NA.87

Date: 30 Mar 17

To,
Dr. Lakshmi Rachakondal
OBGY, Mahatma Gandhi Mission Medical College,
N-6, Cidco, Aurangabad,
Maharashtra 431003, India.

Subject: SIF Binder

Ref.: *CP/04/12: A randomized, open label, parallel-group, active-comparator controlled, multi-center study to evaluate the efficacy and safety of Ulipristal acetate (5 mg tablets), as compared with Leuprolide acetate (3.75 mg intramuscular injection) for 12 weeks, in the preoperative treatment of moderate to severe symptomatic uterine fibroids*

Dear Dr. Lakshmi,

Please note that I am dispatching SIF binder today.

Sr. No.	Document Type	Qty.
1.	**SIF Binder** : Volume 1 and Volume 2	2 Files

Please provide us copy of acknowledgement once you receive the letter.

In case of any clarification required, please feel free to contact me on below mentioned contact details.

Thanking you,

J Patel 30 MAR 17

Ms. Jimi Patel
Clinical Research Associate,
Cliantha Research India Limited Tel: +91-22-66219568 | M: +91-9624345833 | jpatel@cliantha.in

ACKNOWLEDGEMENT RECEIPT (To be completed by Site Staff)		
Letter Reference No.: CP/04/12.NA.87 – SIF Binder / Dr. Lakshmi Rachakondal		
Comments:		
Received By: Sagar Kharat	Role in the Study: SC	Signature & Date: SRK · 03 April 17
Please fax this signed copy of Acknowledgement Receipt at *+91-79-66219549*		

CLINICAL TRIAL AGREEMENT

Date: 19/03/2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

Dr. Anuradha Patil, (MBBS, DNB Plastic Surgery) at MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr. Anuradha Patil as the Principal Investigator:

1. Title: An open label, Two Arms, Comparative, Phase-IV Clinical Study evaluating safety and efficacy of Oratil LZ (combination of Cefuroxime 250mg + Linezolid 600mg) versus Linezolid 600mg in patients with Diabetic Foot Infections.
   Protocol No.: CT-192-CELI-2015

2. The objective of the trial is to compare the safety and efficacy safety and efficacy Oratil LZ (combination of Cefuroxime 250mg + Linezolid 600mg) versus Linezolid 600mg in patients with Diabetic Foot Infections.

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows:

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 14375 plus Laboratory Investigation Charges per patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 0	3000/-
Visit 1	3125/-
Visit 2	4125/-
Visit 3	4125/-

Role and responsibilities of Dr. Anuradha Patil (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 10 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one months. The sponsor expects a total of 10 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects.

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Fax : +91 22 29256599/29256229
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CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) Macleods Pharmaceuticals Ltd. would like to have intermittent report every as required during the course of the study.
12) Macleods Pharmaceuticals Ltd. would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator
13) Contents of the report during the clinical trial should not be revealed to any other company in India or outside India without written permission from Macleods Pharmaceuticals Ltd.
14) The data obtained during the trial could not be published by the principal investigator wherein Macleods Pharmaceuticals Ltd. should be acknowledged. Macleods Pharmaceuticals Ltd. will have the right to use this research paper.
15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

Corporate Office :
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Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.
5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr. Anuradha Patil (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Service
Address: Macleods Pharmaceuticals Ltd
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr. Anuradha Patil
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Authorized Signatory

Dr Sushil Chaudhary
Designation-Director-Grapecity Research Solutions LLP.
Address; Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India.

Signature

Name : Dr. Rajendra Bohra
Designation- Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

MGM's Medical College Aurangabad

Corporate Office :
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Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

CLINICAL TRIAL AGREEMENT

Date: 21.04.2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

I Dr Deepak Sadashiv Bhosle [MBBS,M.D(Grad. Diploma in Diabetes) Mahatma Gandhi Missions medical college & Hospital, N6 Cidco, Aurangabad, 4310003 (MH), INDIA.

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India.

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr Deepak Sadashiv Bhosle as the Principal Investigator:

1. Title: An open label, Two arm, Comparative, Randomized Phase IV Clinical Study evaluating efficacy and safety of Alrista Forte (Epalrestat 150 Mg + Methylcobalmin 1500 Mcg + Pregabalin 150 Mg) Tablet versus Pregabalin 150 Mg Capsule in patients with Diabetic Neuropathy.
   Protocol No.: CT-213-EMP(F)-2016

2. The objective of the trial is to compare the safety and efficacy of Alrista Forte (Epalrestat 150 Mg + Methylcobalmin 1500 Mcg + Pregabalin 150 Mg) Tablet versus Pregabalin 150 Mg Capsule in patients with Diabetic Neuropathy.

Corporate Office :
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Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
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G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 12000 including overhead and Laboratory Investigation Charges as per actual bill for patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	2000/-
Visit 2	2000/-
Visit 3	2500/-
Visit 4	2500/-
Visit 5	3000/-

Role and responsibilities of Dr Deepak Sadashiv Bhosle (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 20 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one months. The sponsor expects a total of 20 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects,

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304-Atlanta Arcade, Marol-Church Road,
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Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) Macleods Pharmaceuticals Ltd. would like to have intermittent report every as required during the course of the study.
12) Macleods Pharmaceuticals Ltd. would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator
13) Contents of the report during the clinical trial should not be revealed to any other company in India or outside India without written permission from Macleods Pharmaceuticals Ltd.
14) The data obtained during the trial could not be published by the principal investigator wherein Macleods Pharmaceuticals Ltd. should be acknowledged. Macleods Pharmaceuticals Ltd. will have the right to use this research paper.
15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.

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5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr Deepak Sadashiv Bhosle (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Services
Address: Macleods Pharmaceuticals Ltd.
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr Deepak Sadashiv Bhosle
Principal Investigator
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Signature

Dr Sushil Chaudhary
Designation-Director- Grapecity Research Solutions LLP.
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

MGM's Medical College Aurangabad

Signature

Name : Dr. Rajendra Bohra
Designation - Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad 431003, Maharashtra, India

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CLINICAL TRIAL AGREEMENT

Date: 21.04.2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

I Dr Prashant Darakh MBBS, DNB (Urology) Gandhi Missions medical college & Hospital, N6 Cidco, Aurangabad, 4310003 (MH), INDIA.

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India.

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr Prashant Darakh as the Principal Investigator:

1. Title: An open label, Prospective, Comparative, Randomized, Clinical Study evaluating efficacy and safety of Treatment A (Tamsulosin 0.4 mg Modified release Capsule) Versus Treatment B (FDC of Deflazacort 30 mg Plus Tamsulosin 0.4 mg Tablet) in the Patients with ureteral stone.
   Protocol No.: CT-203-TaDa(F)-2016

2. The objective of the trial is to compare the safety and efficacy of Treatment A (Tamsulosin 0.4 mg Modified release Capsule) Versus Treatment B (FDC of Deflazacort 30 mg Plus Tamsulosin 0.4 mg Tablet) in patients with ureteral stone.

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Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 12000 including overhead and Laboratory Investigation Charges as per actual bill for patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	4000/-
Visit 2	4000/-
Visit 3	4000/-

Role and responsibilities of Dr Prashant Darakh (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 20 patients. The number of patients can be increased or decreased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one month. The sponsor expects a total of 20 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects,
9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

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10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
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12) Macleods Pharmaceuticals Ltd. would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator
13) Contents of the report during the clinical trial should not be revealed to any other company in India or outside India without written permission from Macleods Pharmaceuticals Ltd.
14) The data obtained during the trial could not be published by the principal investigator wherein Macleods Pharmaceuticals Ltd. should be acknowledged. Macleods Pharmaceuticals Ltd. will have the right to use this research paper.
15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.
5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

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Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr Prashant Darakh (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Services
Address: Macleods Pharmaceuticals Ltd.
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr Prashant Darakh
Principal Investigator
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Signature

Dr Sushil Chaudhary
Designation-Director- Grapecity Research Solutions LLP.
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Signature

MGM's Medical College Aurangabad

Name : Dr. Rajendra Bohra
Designation - Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

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CLINICAL TRIAL AGREEMENT

Date: 21.04.2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

Dr. Rajendra Bohra (MBBS, MS ENT) at MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Dr. Pravin Suryawanshi (Deputy Dean), Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr. Rajendra Bohra as the Principal Investigator:

1. Title: A Two arm, Comparative, Parallel, Randomized, double-blind, double-dummy Clinical study to evaluate and compare the efficacy and safety of Cefrine (combination of cefdinir 300 mg + lactobacillus 60 million cells) Capsule versus Cefuroxime 250 mg Tablet in the treatment of patients with Upper Respiratory Tract Infections.
   Protocol No.: CT-211-CELA(F)-2016

2. The objective of the trial is to compare the safety and efficacy safety and efficacy Cefrine (combination of cefdinir 300 mg + lactobacillus 60 million cells) Capsule versus Cefuroxime 250 mg Tablet in the treatment of patients with Upper Respiratory Tract Infections.

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Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows:

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 12000 plus Laboratory Investigation Charges per patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	4000/-
Visit 2	4000/-
Visit 3	4000/-

Role and responsibilities of Dr. Rajendra Bohra (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 20 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one months. The sponsor expects a total of 20 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects.

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9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) Macleods Pharmaceuticals Ltd. would like to have intermittent report every as required during the course of the study.
12) Macleods Pharmaceuticals Ltd. would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator
13) Contents of the report during the clinical trial should not be revealed to any other company in India or outside India without written permission from Macleods Pharmaceuticals Ltd.
14) The data obtained during the trial could not be published by the principal investigator wherein Macleods Pharmaceuticals Ltd. should be acknowledged. Macleods Pharmaceuticals Ltd. will have the right to use this research paper.
15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.
5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

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It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr. Rajendra Bohra (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Service
Address: Macleods Pharmaceuticals Ltd
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr. Pravin Suryawanshi
Designation- Deputy Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Signature

Name : Dr. Rajendra Bohra
Principal Investigator
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

MGM's Medical College Aurangabad

Signatory

Dr Sushil Chaudhary
Designation-Director-Grapecity Research Solutions LLP.
Address; Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India.

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CLINICAL TRIAL AGREEMENT

Date: 18/03/2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

Dr. Swati Shiradkar (M.B.B.S. M.D. – Consultant Gynecologist) at MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr. Swati Shiradkar as the Principal Investigator:

1. Title: A Prospective, Multicentric, Phase IV Clinical Study evaluating safety and efficacy of Leuprorelin 3.5mg Injection plus Enzomac Tablet (Trypsin 96 mg + Bromelain 180 mg + Rutoside Trihydrate 200 mg) versus Leuprorelin 3.5mg Injection in the treatment of patients diagnosis with Endometriosis.
   Protocol No.: CT-205-LEEN-2016

2. The objective of the trial is to compare the safety and efficacy safety and efficacy of Leuprorelin 3.5mg Injection plus Enzomac Tablet (Trypsin 96 mg + Bromelain 180 mg + Rutoside Trihydrate 200 mg) versus Leuprorelin 3.5mg Injection in the treatment of patients diagnosis with Endometriosis.

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows:

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Research Centre :
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Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 14375 plus Laboratory Investigation Charges per patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	4125/-
Visit 2	5125/-
Visit 3	5125/-

Role and responsibilities of Dr. Swati Shiradkar (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 12 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one months. The sponsor expects a total of 12 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
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9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

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10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
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15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.
5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

MACLEODS PHARMACEUTICALS LIMITED

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr. Swati Shiradkar (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Service
Address: Macleods Pharmaceuticals Ltd
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr. Swati Shiradkar
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Authorized Signatory
Dr Sushil Chaudhary
Designation-Director-
Grapecity Research Solutions LLP.
Address; Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India.

Signature

Name : Dr. Rajendra Bohra
Designation- Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

MGM's Medical College Aurangabad

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
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Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA63828731129968P
Certificate Issued Date	:	05-Jul-2017 10:59 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BANGALORE8/ KA-BA
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Description	:	CLINICAL STUDY AGREEMENT
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Sri Siddhi Vividhoddesha Souharda Sahakari Niyamita (R) Sahakranagar B'lore-92

Please write or type below this line

CLINICAL STUDY AGREEMENT

between

ASTRAZENECA PHARMA INDIA LTD

And

Mahatma Gandhi Mission Medical College & Hospital,

And

Dr. Prashant P. Udgire

CLINICAL STUDY AGREEMENT

between

ASTRAZENECA PHARMA INDIA LTD

Block N1, 12th Floor,

Manyata Embassy Business Park,

Rachenahalli, Outer Ring Road,

Bangalore 560045, Karnataka, INDIA

Phone: +91-80- 67748600, Fax: +91-80- 67748857

And

Mahatma Gandhi Mission Medical College & Hospital,

N-6 CIDCO, Aurangabad-431003 Maharashtra, India

And

Dr. Prashant P. Udgire

Assistant Professor Department of Cardiology, Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India

Phone Number: 9503181111

STUDY NAME: A Study to Evaluate the Effect of Dapagliflozin on Incidence of Worsening Heart Failure or Cardiovascular Death in in Patients with Chronic Heart Failure with Reduced Ejection Fraction.

STUDY CODE: D1699C00001

STUDY SITE NUMBER: 3524

CLINICAL STUDY AGREEMENT

PARTIES

(1) AstraZeneca Pharma India Ltd, a company incorporated in India, whose registered office is at Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore-560045, Karnataka, India (the "**Company**");

(2) Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India (the "**Institution**"); and

(3) Dr. Prashant P. Udgire, Assistant Professor Department of Cardiology, Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India (the "**Principal Investigator**"),

together the "**Parties**" and each a "**Party**".

BACKGROUND

(a) The Company intends to conduct the Study.

(b) The Institution has the appropriate facilities and personnel, and the Principal Investigator has the necessary qualifications, training, experience and expertise, to conduct the Study.

(c) The Company wishes to engage the Institution and the Principal Investigator to conduct the Study on its behalf.

EFFECTIVE DATE

The effective date of this Agreement shall be the date on which the last of the Parties signs this Agreement.

AGREED TERMS

1. DEFINITIONS

Unless otherwise specifically provided in this Agreement, capitalised terms shall have the meanings set forth in Appendix A.

2. CONDUCT OF THE STUDY

2.1 The Company hereby engages the Institution and the Principal Investigator to conduct the Study.

2.2 The Institution and the Principal Investigator shall conduct the Study at the Study Site in accordance with this Agreement, the Protocol and all Applicable Laws.

2.3 The Institution and/or the Principal Investigator will not deviate from the Protocol unless in order to eliminate an immediate hazard to Subjects. The Institution and/or Principal Investigator shall promptly notify the Company upon becoming aware of the deviation. The Company and/or Principal Investigator will notify the Ethics Committee of deviations in accordance with Applicable Laws.

3. RESPONSIBILITIES OF THE COMPANY

AstraZeneca AB, a company incorporated in Sweden whose registered office is at SE-151 85 Södertälje, Sweden has assumed the role of sponsor of the Study, and has engaged the Company to conduct and manage the Study in accordance with this Agreement, the Protocol and Applicable Laws, and has authorised it to enter into this Agreement.

4. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

4.1 The Principal Investigator shall be responsible for the day-to-day conduct of the Study, including training, leading and supervising Study Site Staff.

4.2 The Principal Investigator shall:

4.2.1. ensure that he/she is appropriately qualified by training and expertise, and obtain and maintain all contractual, regulatory and ethical approvals, notifications and authorisations required (including approvals from entities by which he/she is employed or to which he/she is affiliated), to enter into this Agreement and conduct the Study in accordance with Applicable Laws (and provide evidence of the same to the Company on request);

4.2.2. provide, or ensure that the Institution provides, appropriately qualified Study Site Staff, and ensure that they are supervised and are made aware of, and comply with the terms of this Agreement, and, as appropriate, with the Protocol and Applicable Laws;

4.2.3. obtain and maintain all Ethics Committee approvals required for the conduct of the Study, keep the Company informed of the progress of all applications for the same and provide Company with copies of such approval(s) on request.

4.2.4. ensure that any amendments to the Protocol are approved by the Ethics Committee and/or the Regulatory Authority prior to implementation in accordance with Applicable Laws, and ensure to maintain all approvals from the relevant Regulatory Authority, if not instructed otherwise by Company;

4.2.5. once all necessary regulatory and ethical authorisations, notifications and approvals have been obtained, use his/her reasonable endeavours to enrol the target number of Subjects into the Study. However, the Subject enrolment period may be extended or shortened and the number of Subjects that Institution

and Principal Investigator may enrol in the Study may be changed, at the Company's sole discretion;

4.2.6. ensure that informed consent is obtained from each Subject, and maintained, in accordance with the Protocol and Applicable Laws, such consent to include authorisation for the use and disclosure of the Subject's protected health information in accordance with Applicable Laws;

4.2.7. report to the Sponsor all Adverse Events in the form and within the time frame set out in the Protocol and in accordance with all Applicable Laws;

4.2.8. provide such other assistance in connection with the Study as the Company may reasonably request from time to time; and

4.2.9. ensure that each subject: a) receives patient engagement communications and ongoing study communications promptly upon receipt by the Company or its Designee prior to Study Closure; b) receives the post study communications provided by the Company or its Designee no later than 2 months after Study Closure.

4.3 Principal Investigator and/or Study Site Staff may be invited to attend and participate in meetings relating to the Study. The Parties agree that there will be no additional compensation for attendance or participation at such meetings by the Principal Investigator or any Study Site Staff. If the Principal Investigator and/or Study Site Staff are required to perform any additional tasks, over and above those required for the conduct of the Study, the terms and obligations for the provision of such services shall be subject to a separate agreement.

5. RESPONSIBILITIES OF THE INSTITUTION

5.1 The Institution shall:

5.1.1. provide appropriate premises, facilities and equipment for the Study, including the Study Site, and provide such assistance, resources and cooperation as the Company may reasonably request in connection with the Study;

5.1.2. provide, or ensure that the Principal Investigator provides, appropriately qualified Study Site Staff and ensure that they are made aware of, and comply with, the terms of this Agreement, the Protocol, and Applicable Laws; and

5.1.3. notify the Company immediately if the Principal Investigator ceases to be employed by or associated with the Institution, or is otherwise unable to act or continue to act as the Principal Investigator.

6. STUDY DRUG AND MATERIALS

6.1 The Company shall use commercially reasonable efforts to supply (or procure the supply), at no cost to Institution or Principal Investigator, the quantities of Study Drug required to conduct the Study in accordance with the Protocol and Applicable Laws.

6.2 The Institution and the Principal Investigator shall ensure that the Study Drug is stored, dispensed and administered under proper conditions and in accordance with the Protocol, the Applicable Laws and, where relevant, the Company's instructions.

6.3 The Institution and/or Principal Investigator shall promptly report to the Company any adverse findings in relation to any Study Drug delivered to it, and the Company shall take such steps as are reasonably practicable in the circumstances to provide replacement Study Drug or otherwise to minimise the impact on the Study. If the Company and/or any Regulatory Authority deem that a recall of Study Drug is required, the recall strategy shall be developed by the Company and followed by the Institution and the Principal Investigator with strict regard to the requirements in terms of timing and/or any other conditions imposed.

6.4 The Study Drug must be used only for the purposes outlined in the Protocol and, neither the Institution nor the Principal Investigator shall use, supply or otherwise make available any Study Drug for any other purposes, nor engage in any promotion or commercialisation of Study Drug for any unauthorised indication.

6.5 The Principal Investigator shall maintain complete and accurate records relating to the Study Drug consistent with the Protocol and as required by Applicable Laws. At the completion or termination of the Study or earlier termination of this Agreement all remaining Study Drug shall, at the Company's option, be returned to the Company (at Company's expense) or disposed of in accordance with Applicable Laws.

6.6 The Company will provide the Institution and the Principal Investigator with the Materials required for the conduct of the Study. The Company shall retain all rights, title and interest in and to the Materials unless otherwise agreed by the Company in writing. The Materials may only be used by the Institution, the Principal Investigator and the Study Site Staff to the extent required for the conduct of the Study.

6.7 The Institution and the Principal Investigator shall be responsible for keeping any Materials in good repair and in such condition as they were on the date of delivery (fair wear and tear excepted). The Materials shall be kept and operated in a suitable environment and used only for the purpose for which they are intended, by trained staff in accordance with any instructions provided by the Company.

6.8 At Study Site Closure or at Company's earlier request, Institution and Principal Investigator shall promptly return all Materials to the Company, unless the Parties agree that Institution or Principal Investigator shall acquire the Materials for their fair market value. Any such acquisition of Materials shall be subject to a separate agreement between the relevant parties.

7. STUDY DOCUMENTATION

7.1 The Institution and the Principal Investigator shall compile and maintain all Study Documentation, the investigator study file (including but not limited to copies of CRFs, data queries and Adverse Event reports (if applicable)) and all other documents required under this Agreement, in accordance with this Agreement, the Protocol and Applicable Laws.

7.2 The Institution and the Principal Investigator shall make the Study Documentation available for the Company and the Regulatory Authorities in accordance with Applicable Laws. The Study Documentation shall be retained for a minimum of fifteen (15) years, or longer in accordance with the Applicable Laws, after the Study Closure.

8. MONITORING AND AUDIT BY THE COMPANY

8.1 The Institution and the Principal Investigator shall permit the Company or its Designee to access the Study Site during normal business hours and on reasonable notice in order for the Company to monitor that the Study has been and is being conducted in accordance with the Protocol and Applicable Laws.

8.2 The Institution and the Principal Investigator agree to cooperate fully with the Company during monitoring and audits, including making all Study Documentation available for review by the Company or its Designee (subject to reasonable safeguards for the protection of personal data and medical confidentiality as set out in Clause 13).

8.3 The Institution and the Principal Investigator shall ensure that all questions and action items arising from monitoring and audit pursuant to this Clause 8 are resolved within such reasonable period as the Parties may agree.

9. INSPECTION BY THE REGULATORY AUTHORITIES

9.1 A Party shall notify all other Parties as soon as reasonably possible (and in any event within two working days) following:

9.1.1. receipt of any request from a Regulatory Authority for an inspection of the Study Site (or the conduct of any inspection if without notice); or

9.1.2. receipt of any written or oral enquiries from a Regulatory Authority, regarding any aspect of the activities pursuant to this Agreement or the conduct of the Study,

and shall provide copies of all associated correspondence with the Regulatory Authority.

9.2 To the extent reasonably practicable, the Institution and the Principal Investigator shall allow the Company or its Designee to attend any inspection by a Regulatory Authority. If the Company or its Designee are not allowed to attend any such inspection, the Institution and/or Principal Investigator shall provide the Company with a detailed summary of the Inspection as soon as reasonably practicable thereafter.

9.3 The Institution and Principal Investigator shall notify the Company of any violation or deficiency noted by a Regulatory Authority. The Parties shall cooperate with each other in relation to the preparation of any response.

10. PAYMENTS

10.1 In consideration of the services rendered under this Agreement, the Company shall pay the Institution and/or the Principal Investigator in accordance with Appendix B.

10.2 Payment will not be made until the Company has received an invoice or such any other documentation as set out in Appendix B evidencing that the relevant services have been completed. The Company shall pay any invoices within sixty (60) days of the date of receipt by the Company, PROVIDED THAT if any amount included in the invoice is disputed, the Company shall not be required to pay the disputed amount until the dispute is resolved in accordance with this Agreement.

10.3 The Parties acknowledge that the amounts to be paid by the Company under this Agreement are reasonable, represent fair market value and are for services actually performed by the Institution, the Principal Investigator and/or Study Site Staff for the work under this Agreement and that neither the Institution, the Principal Investigator nor the Study Site Staff have received any other compensation or inducement from the Company in connection with the Agreement or their participation in the Study.

10.4 The Company shall deduct or withhold from the amounts payable any taxes that it is required by Applicable Laws to deduct or withhold. All payments made by the Company under this Agreement are inclusive of value added taxes, sales taxes or similar taxes. The Institution will be responsible for all such taxes with respect payments under this Agreement.

10.5 The Institution and the Principal Investigator shall keep and maintain accurate and reasonably detailed financial records in connection with the activities performed under this Agreement. Upon request, the Company shall have the right to audit such financial records to test compliance with this Agreement.

11. INTELLECTUAL PROPERTY

11.1 Except as expressly set out in this Agreement, no Party shall acquire any right, title or interest in or to the Intellectual Property of any of the other Parties or their licensors.

11.2 The Company shall own all rights and title in any Intellectual Property arising from the Study or relating to the Study Drug, any Developed Technology and the Study Documentation, except to the extent that the Institution and Principal Investigator are required to retain any Study Documentation in accordance with GCP and the Applicable Laws. The Institution and the Principal Investigator shall promptly disclose any such Intellectual Property to the Company in writing or in such other format as the parties may agree.

11.3 To the extent capable of prospective assignment, the Institution and the Principal Investigator hereby assign to the Company (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 11.2 above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution and the Principal Investigator shall assign, and shall procure that the Study Site Staff shall assign, such Intellectual Property to the Company (or its Designee) on creation.

11.4 The Institution and the Principal Investigator shall, and shall ensure that the Study Site Staff take all steps as the Company may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 11.

11.5 The Company hereby grants to the Institution a perpetual, royalty-free non-exclusive licence to use the Intellectual Property arising only from the Study for internal research and educational purposes only, and with no right to grant sub-licences. The provisions of Clauses 12 and 14 of this Agreement shall continue to apply in relation to any such licence.

12. CONFIDENTIAL INFORMATION

12.1 Subject to Clauses 12.2 and 12.3, each Party shall at all times keep confidential the Confidential Information. Each Party shall safeguard the other Party's Confidential Information with at least the same level of care as it affords to its own Confidential Information, and shall not use any other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement. All Study Site Staff shall be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement.

12.2 The obligations on each Party set out in Clause 12.1 shall survive for ten (10) years after the expiry or termination of this Agreement, but shall not apply to any information which:

12.2.1. was in that Party's possession (with full right to disclose) prior to receiving it from another Party, as demonstrated by written records;

12.2.2. is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or

12.2.3. it can demonstrate was developed independently without reference to the Confidential Information, or was received from a third party who had the right to disclose such information in a non-confidential manner.

12.3 A Party may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the disclosing Party gives the affected Party as much notice of such disclosure as possible; and (ii) the disclosing Party complies with the affected Party's reasonable directions for taking legally available steps to resist or narrow such requirement (at the affected Party's reasonable

expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.

12.4 The Parties acknowledge that damages alone would not be an adequate remedy for the breach of any of the terms of Clause 12, and that in the event of a breach or threatened breach the Party that initially disclosed the Confidential Information shall be entitled to seek equitable relief and/or injunctive relief concerning any threatened or actual breach (in addition to any other rights and remedies it may have under this Agreement or otherwise).

13. PERSONAL DATA AND BIOLOGICAL MATERIALS

13.1 The Parties agree to comply with all Applicable Laws in relation to the protection of the personal data of Subjects, the Principal Investigator and Study Site Staff. The Institution and the Principal Investigator shall maintain appropriate technical and organisational security measures to protect the confidentiality and security of Subjects' personal data.

13.2 The Institution and Principal Investigator shall ensure that any collection, handling, transportation and retention of Biological Materials in connection with the Study is carried out in accordance with the Protocol, the informed consents of Subjects, and all Applicable Laws and in such a way as to ensure that the security, integrity, quality and identity of the Biological Materials is maintained at all times.

14. RIGHTS TO PUBLICATION

14.1 The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study, as indicated in this Section 14. If this Study is part of a multi-centre clinical trial, Institution and Investigator agree not to independently publish the results of the Study until first occurrence of one of the following: (i) multi-centre primary Publication is published; (ii) no multi-centre primary publication is submitted within two years after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-centre primary Publication. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors (ICMJE) guidelines, (ii) not be false or misleading, (iii) comply with all Applicable Laws, (iv) not be made for any commercial purpose.

14.2 The Institution and/or the Principal Investigator shall provide the Company with copies of any materials relating to the Study, or the Developed Technologies that either intends to publish (or submit for publication) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.

14.3 At the request of the Company, the Institution and/or the Principal Investigator:

14.3.1. shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and

14.3.2. shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Company receives the material to allow the Company to take such measures as the Company considers necessary to preserve its proprietary rights and/or protect its Confidential Information.

14.4 The Institution and the Principal Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or the Developed Technologies, as well as in any financial disclosure information relating to the Study: "AstraZeneca sponsored this clinical trial." A copy of any publications and presentations relating to the Study, the Study Documentation and/or the Developed Technologies shall be provided to the Company on publication or presentation, and the Company shall be entitled to make copies of and distribute the publication or presentation as it considers necessary.

14.5 Subject to Clause 14.4, no Party shall mention or otherwise use the name, trade mark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party; provided, however, that the Company shall have the right to identify the Institution, the Principal Investigator and the responsible Study Site Staff in any Study recruitment activities or other Study-related meetings.

14.6 The Company has a long-standing commitment to transparency, and the Institution and the Principal Investigator acknowledge that the Sponsor shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format (including www.astrazenecaclinicaltrials.com), and/or provide such results to the Regulatory Authorities and in accordance with Applicable Law.

14.7 If the Company invites the Principal Investigator to be an author of a Company-managed publication, the Principal Investigator shall agree to comply with ICMJE authorship criteria. The Principal Investigator shall direct, draft and/or review the proposed publication, approve the final version of the publication to be published and retain full responsibility for its content. Company financial support for this research, any other financial relationship with Company, as well as any other relevant financial relationships as required by the journal or congress shall be disclosed in the publication. Any authorship, medical writing, editorial or logistical support provided to the Principal Investigator or the Institution by the Company in respect of publication shall be subject to the Company's publications policy, details of which are available at www.astrazeneca.com. No compensation shall be provided in respect of any such authorship.

15. INSURANCE AND INDEMNITY

15.1 Each of the Parties shall ensure that adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws, in particular towards Subjects for personal injury arising as a result of participation in the Study.

15.2 The Company agrees to indemnify the Institution and the Principal Investigator against all direct costs, claims, liabilities, penalties or expenses (including reasonable legal fees and disbursements), (collectively "**Losses**") arising out of or relating to the conduct of the Study.

15.3 The Company's indemnity under Clause 15.2 will not apply to the extent that such Losses arise from or relate to (a) any breach of this Agreement or Applicable Laws by the Institution and the Principal Investigator, or (b) any negligence, recklessness or willful act or omission by the Institution, the Principal Investigator or the Study Site Staff in the performance of their obligations under this Agreement.

15.4 If any third party makes a claim, or notifies an intention to make a claim, against the Institution or the Principal Investigator which may reasonably be considered likely to give rise to a liability under this indemnity (a "**Claim**"), the Institution and/or the Principal Investigator shall:

15.4.1. as soon as reasonably practicable, give written notice of the Claim to the Company, specifying the nature of the Claim in reasonable detail;

15.4.2. not make any admission of liability, agreement or compromise in relation to the Claim without the prior written consent of the Company, such consent not to be unreasonably withheld; and

15.4.3. take such action as the Company may reasonably request to avoid, dispute, compromise or defend the Claim (including granting the Company full conduct and control of the claim).

16. COMPLIANCE, TRANSPARENCY, ANTI-BRIBERY, ANTI-CORRUPTION AND CONFLICTS OF INTEREST

16.1 The Parties will ensure that neither they, nor any of their officers or employees, directly or indirectly offer, make, accept or request any Payments or Transfers of Value to or from any official or other person, that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation, including but not limited to inducements, bribes, kickbacks and facilitation payments.

16.2 The Institution and the Principal Investigator warrant that neither they nor any of their Study Site Staff have engaged in any conduct that has resulted or may result in a criminal conviction, nor are currently excluded, debarred, suspended, or otherwise ineligible to participate in the Study and/or government health care programs in any country. The Institution and the Principal Investigator agree to notify the Company immediately in the event they become aware that they or any of their Study Site Staff are being investigated by any Regulatory Authority.

16.3 The Institution and the Principal Investigator acknowledge and agree (and shall be responsible for obtaining consent from the Study Site Staff) that the Company and/or its Affiliates may store, use and publicly disclose information (including personal data) about

the Institution, the Principal Investigator and the Study Site Staff and certain Payments or Transfers of Value provided to them in relation to the Study as required by Applicable Laws. Certain Payments or Transfers of Value may also be disclosed on public websites.

16.4 The Institution and the Principal Investigator declare that neither the Principal Investigator, nor any member of the Study Site Staff, is subject to any conflicting obligations or legal impediments and/or has any financial, contractual or other interests in the outcome of the Study that might interfere with the performance of the Study or that is likely to affect the reliability and robustness of the data generated in the Study. The Principal Investigator shall inform the Company immediately upon learning of the existence of any financial arrangement or interest between the Principal Investigator and the Company.

16.5 If during the term of this Agreement or within 2 years of its termination the Principal Investigator (i) joins or participates in any committee that sets formularies or develops clinical guidelines, or (ii) is involved in any decision or recommendation relating to the adoption of any products of the Company or its Affiliates for clinical use in any local or national health care service, the Principal Investigator will disclose to such committee the existence and nature of this Agreement and will follow the disclosure obligations and procedures set forth by the committee.

17. TERM AND TERMINATION

17.1 This Agreement will remain in effect until (a) termination or completion of the Study, close-out of the Study Site, receipt of all Study Documentation by the Company, and completion of the obligations of the Parties under the Protocol, or (b) earlier termination in accordance with this Agreement.

17.2 Any Party may terminate this Agreement with immediate effect at any time upon written notice to all other Parties if:

17.2.1. on reasonable grounds it believes the Study should cease in the interest of the health, safety or well-being of Subjects;

17.2.2. any Party or any of their employees, agents, or sub-contractors commits any of the acts referred to in Clause 16.1 or any offence under the applicable transparency or anti-corruption laws in relation to this Agreement or the Study, or any breach of the warranty given in Clause 16.2;

17.2.3. any other Party commits a material breach of any of its obligations under the Agreement and fails to remedy such breach (where possible) within thirty (30) days of written notice from a non-defaulting Party; or

17.2.4. any step, application, order, proceeding or appointment is taken or made by or with respect to any other Party for distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, if that Party is unable to pay its debts or if any event occurs which, under the applicable law of any

jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Clause 17.2.4.

17.3 The Company may terminate or suspend the Study and/or terminate this Agreement immediately for any reason whatsoever upon written notice to Institution and Principal Investigator.

17.4 The Company shall have no liability to the Institution or the Principal Investigator for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination. For the avoidance of doubt, (except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution or Principal Investigator) the Company shall, upon receipt of invoices and other supporting documentation, pay to the Institution and/or Principal Investigator all costs incurred and falling due for payment up to the date of termination and all non-cancellable costs committed before receipt of notice of termination, provided that such commitments are reasonable and necessarily incurred by the Institution or Principal Investigator for the performance of the Study prior to the date of termination and agreed with the Company.

17.5 Upon notice of termination of this Agreement:

17.5.1. the Parties shall take all reasonable steps to minimise any inconvenience or harm to the Subjects; and

17.5.2. the Institution and the Principal Investigator shall:

17.5.2.1 immediately -cease enrolment of Subjects into the Study; and

17.5.2.2 promptly provide to the Company all Study Documentation (except where required to be retained pursuant to Applicable Laws), the Company's Confidential Information and any Materials provided by the Company in connection with the Study.

17.6 The following Clauses shall survive the termination or expiry of this Agreement to the extent necessary to preserve such rights and obligations: Clause 4.2.9 (Study Communication); Clause 6 (Study Drug and Materials); Clause 7 (Study Documentation); Clause 8 (Monitoring and Audit by Company); Clause 9 (Inspection by the Regulatory Authorities); Clause 10 (Payments), in respect of any rights to payment arising prior to termination; Clause 11 (Intellectual Property); Clause 12 (Confidential Information); Clause 13 (Personal Data and Biological Samples); Clause 14 (Rights to Publication); Clause 15 (Insurance and Indemnity); Clause 16 (Compliance, Transparency, Anti-Bribery, Anti-corruption and Conflicts of Interest); Clause 17.3 (Term and Termination); and Clause 18 (General).

18. GENERAL

18.1 **Force Majeure** - No Party shall be liable to any other for any delay or non-performance of its obligations under this Agreement arising from any Force Majeure Event. In the

event of a Party being so delayed or prevented from performing its obligations, such Party shall: (i) give notice in writing of such delay or prevention to the other Parties as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause of such delay or prevention and its estimated duration; (ii) use commercially reasonable efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement; and (iii) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

18.2 **Assignment, Subcontracting** - The Principal Investigator and the Institution may not assign, delegate, subcontract, sublicense or otherwise transfer any or all of their rights and obligations under this Agreement without the prior written consent of the other Parties. The Company shall be entitled to assign, delegate, sublicense or otherwise transfer its rights and obligations under this Agreement to any Affiliate, any external service providers such as contract research organisations retained to assist the Company in managing and monitoring the Study, and to any successor in interest to all or substantially all of the business to which this Agreement relates. The Company shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates. Any assignment in violation of this Agreement shall be null and void.

18.3 **No Partnership** - Nothing in this Agreement shall create, or be deemed to create a partnership, joint venture, employer/employee, contractor/contractee, or other relationship between the Parties other than the contractual relationship expressly provided for in this Agreement.

18.4 **Waiver** - No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that (or any other) right or remedy, nor shall it preclude or restrict its further exercise. In addition, no single or partial exercise of any such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.

18.5 **Construction** - The Parties acknowledge and agree that they have reviewed, negotiated and jointly drafted this Agreement and that it should be construed without regard to the Party or Parties responsible for its preparation.

18.6 **Invalidity** - If any provision of this Agreement is held by any court or other competent authority to be illegal, invalid or unenforceable in whole or in part, this Agreement shall continue to be valid as to its other provisions, and if possible the affected provision should be modified to the minimum extent necessary to make it valid, legal and enforceable.

18.7 **Inconsistency** - In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

18.8 **Notices** - Any notice to be given by any Party under or in connection with this Agreement must be in writing and shall be: (a) delivered by hand or by courier; (b) sent by pre-paid recorded (i.e. signed for) post; or (c) sent by fax, to the addresses set out at the start of this Agreement or such addresses or numbers as may be notified to the other Parties from time

to time. Notices sent in accordance with this Clause are to be deemed to have been received (i) if delivered by hand or by courier, when left at the address referred to above; (ii) if sent by post, three business days after posting; (iii) if sent by fax, when transmitted.

18.9 **Entire agreement** - This Agreement together with the Appendices (all of which are incorporated by reference) constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior agreements, whether written or oral, with respect to that subject matter.

18.10 **Amendments** - Any amendment or modification to this Agreement must be in writing and signed by authorised representatives of each Party.

18.11 **Counterparts** - This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same agreement. The Parties agree that execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defence or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

18.12 **Governing law** - This Agreement and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of India without regard to the conflicts of law principles thereof. The Parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter (including non-contractual disputes or claims).

19. SUB – CONTRACTOR

The Institution and Principal Investigator shall be permitted to use SMO as its Sub-contractor to [manage Study Site staff, Investigator grant, Institutional overhead and process payments made by AstraZeneca under this Agreement per APPENDIX B]. Except for the foregoing, the Institution and Principal Investigator shall not engage or make use of Subcontractors for the purpose of performing its obligations under this Agreement except as expressly authorized by AstraZeneca in writing, provided that any such authorization by AstraZeneca shall not be deemed to be a waiver of AstraZeneca rights with respect to any failure of the Institution and Principal Investigator to conduct its activities under this Agreement. Any such permitted subcontract shall be subject to the applicable terms and conditions of this Agreement, including Clause 12, Clause 16, Clause 17 and Clause 18, and, upon AstraZeneca request, the Institution and Principal Investigator shall require any such Subcontractor to enter into an undertaking, pursuant to which the terms and conditions of this Agreement shall apply directly between such Subcontractor and AstraZeneca prior to disclosing to such Subcontractor any of AstraZeneca's Confidential Information; provided, however, that no such subcontract shall release the Institution and Principal Investigator from any of its obligations under

this Agreement except to the extent such obligations are satisfactorily performed by such Subcontractor in accordance with this Agreement. The Institution and Principal Investigator shall remain at all times responsible to AstraZeneca for the performance and observance of all its obligations under this Agreement (including by Subcontractors). The Institution and Principal Investigator shall procure that all Subcontractors comply with this Agreement. The Institution and Principal Investigator shall adequately assess and provide ongoing oversight of Subcontractors, in order to ensure that the Subcontractor complies with this Agreement. The express reference to a Subcontractor in any provision of this Agreement is for emphasis only and shall not mean that the absence of an express reference to a Subcontractor in another provision means that the provision does not apply to a Subcontractor.

AGREED by the Parties on the dates indicated below.

SIGNED for and on behalf of
AstraZeneca Pharma India Ltd

Signature

Name: Tapankumar M Shah

Title: SMM-India Country Head

Date: 05 July 2017

SIGNED for and on behalf of
Mahatma Gandhi Mission Medical College & Hospital, Aurangabad

Signature

Name: DR. RAJENDRA B. BOHRA

Title: DEAN

Date: 27 July 2017

SIGNED by
Principal Investigator

Signature

Name: DR PRASHANT PRABHAKAR UDGIRE

Title: P.I.

Date: 12/07/2017

APPENDIX A - DEFINITIONS

"**Adverse Event**" shall have the meaning set out in the Protocol.

"**Affiliate**" means any business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party, with "control" meaning in the case of a company, direct or indirect ownership of 50% or more of the voting interest in such company, and in the case of a partnership the right to a share of more than half the assets, or of more than half the income of the partnership.

"**Applicable Laws**" means all applicable international, national, regional and local laws, rules, regulations and guidance including without limitation Regulatory Authority rules and regulations, decisions and industry codes (including any modification or re-enactment thereto) applicable to the Study and the activities or interactions under this Agreement, including Good Clinical Practice, and all generally accepted standards of good laboratory practice, good clinical practice and good medical practice.

"**Biological Materials**" means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells.

"**Confidential Information**" means (i) the terms of this Agreement; and (ii) any business, employee, patient or customer information or data in any form which is disclosed or otherwise comes into possession of a Party, directly or indirectly, as a result of this Agreement and which is of a confidential or proprietary nature (including, without limitation, the Study Documentation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications systems, costs and prices, wage rates, records, finances and personnel).

"**Case Report Form**" or "**CRF**" means a printed document ("pCRF"), optical or electronic document ("eCRF") or database designed to record all of the information to be reported to the Company on each Subject, as required by the Protocol.

"**Designee**" means any person designated by the Company in writing who undertakes activities on behalf of the Company in relation to the Study, which may include an Affiliate.

"**Developed Technology**" means any inventions, discoveries, improvements or developments made by the Institution, the Principal Investigator or any Study Site Staff (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to the Study Drug, or the use thereof.

"**Ethics Committee**" means the independent institutional, regional, national or supranational committee or review board-responsible for ensuring the protection of rights, safety and well-being of human subjects in a clinical study, and for reviewing and approving/providing an opinion on the Protocol, the suitability of the investigator(s), the Study Site(s), the Subject recruitment materials and methods, and informed consent forms.

"Force Majeure Event" means any circumstance beyond a Party's reasonable control, including acts of war or other action of military forces, terrorism, riot, civil commotion, sabotage, vandalism, accident, fire, flood, acts of God, strike, lock-out or other industrial disputes (whether or not involving employees of the relevant party) or legislative or administrative interference and which could not have been avoided or mitigated by the exercise of reasonable care by that Party.

"**Good Clinical Practice**" or "**GCP**" means the International Conference on Harmonisation Guideline for good clinical practice (including any modification or re-enactment thereto).

"**Intellectual Property**" means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

"**Materials**" means any equipment, materials (excluding Study Drug), documents, data, software and information supplied by or on behalf of, or purchased at the expense of, the Company, in connection with the Study, as described and set out in the Protocol and this Agreement.

"**National Coordinating/Lead Investigator**" means the Principal Investigator who, by the Company, has been assigned the responsibility to coordinate all principal investigators across all Study Sites within one country>>

"**Payment or Transfer of Value**" means a direct or indirect transfer of *anything* of value, whether cash or in kind in connection with the development or sale of medical products. "Value" shall mean the discernible economic value on the open market. A direct Payment or Transfer of Value is one made directly by a company for the benefit of a recipient. An indirect Payment or Transfer of Value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

"**Protocol**" means the clinical study protocol that has been approved by the relevant Ethics Committee, which describes the Study, including all amendments thereto as the Parties may from time to time agree in writing.

"**Regulatory Authority**" means any international, national, regional or local agency, authority, department, inspectorate, minister, ministry official, parliament, public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement, the Study, or the Parties.

"**Site Closure**" means the date of receipt by the Principal Investigator of the site closure visit report from the Company.

"**Study Closure**" the date of publishing the Clinical Study Report as communicated by the Company.

"**Sponsor**" means the company, as identified in Clause 3, which takes responsibility for the initiation, management or conduct of the Study in accordance with Applicable Laws.

"**Study Documentation**" means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study and/or Study Drug, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

"**Study**" means the clinical study stated on the front page of this Agreement, as further described in the Protocol.

"**Study Drug**" means the investigational medicinal product(s), any placebo and any comparator drug(s) being studied or tested in the Study as set out in the Protocol.

"**Study Site(s)**" means the premises where Study related activities are conducted, as identified in the Protocol.

"**Study Site Staff**" means all those investigators, sub-investigators, employees, agents, students, sub-contractors and others who are engaged by the Institution and/or the Principal Investigator in the conduct of the Study, including any such persons at Study Site.

"**Subject**" means a person recruited to participate in the Study in accordance with the Protocol and Applicable Laws.

APPENDIX B - PAYMENT

The Company shall compensate the Institution for each Subject that completes the Study in accordance with the Component table below.

1: Per Subject Compensation:

Activity	**Compensation per Subject**
Visit 1: Enrolment	17000
Visit 2: Randomization	20000
Visit 3:	15000
Visit 4:	15000
Visit 5:	15000
Visit 6:	15000
Visit 7:	17000
Visit 8:	17000
Visit 9:	15000
Visit 10:	14000
Visit 11:	14000
Visit 12:	14000
Premature Treatment Discontinuation Visit (PTDV):	11000
Study Closure Visit (SCV)	12000
TOTAL RESEARCH GRANT (if all on-site, in-person, 12 visits and PTDV/SCV visits are completed per protocol.	**2,11,000/-** (this amount would vary based on actual number of on-site, in-person, visits completed by each patient per protocol.)
modified follow-up visit i.e. less frequent visits and or regular telephone contacts and or a contact at study closure and or other means (per protocol in case the patient refuses to continue on-site, in-person, study visits in case of premature treatment discontinuation but agrees to undergo modified telephonic follow-	**1500** (this is an optional component and payment for this will be provided if it is actually performed. This is not payable for routine telephonic follow up calls made to the patient.)

up per protocol section **3.9.3.2**)	

2. MEDICAL MANAGEMENT AND COMPENSATION FOR TRIAL RELATED INJURIES AND RESCUE THERAPY	
Medical management of trial related injuries per schedule Y.	On actuals against original bills. This is towards the cost that patient may have incurred for the management of a trial related injury.
Compensation for trial related injuries per schedule Y.	As directed by the Drugs Controller General (India)

The Company shall be entitled to withhold compensation in respect of Subjects whose visit data is incomplete, missing in eCRF or 'lost to follow-up' as a result of any failure by the Institution or the Principal Investigator to comply with their obligations under this Agreement.

Reimbursement will not be given for Subjects enrolled who do not meet all inclusion and exclusion criteria, unless otherwise approved by the Company, and the Institution will not be compensated for any Protocol violations, unless otherwise approved by the Company.

The Company shall additionally compensate the Institution and the Principal Investigator for the activities set out in the table below.

activities set out in the table below.

3. ADDITIONAL COSTS	
Additional Fees	**Amount in INR**
Subject expenses for travelling and/or reimbursement:	Up to a maximum of INR 2000 per visit
Study Co-ordinator fees:	INR 30,000 per randomized patient
Sub-Investigator Fee	INR 2,000/ per subject per actual visit completed (only applicable for Onsite visits and not applicable for modified follow up visits)
Laboratory Investigations	As per actuals
Internet Charges	INR 2,000 per month (From First Subject in to Data Base Lock)
Administrative costs (eg: phone/fax and courier etc.):	INR 2,000 per randomized subject.
Equipment support (eg: AV recording,	INR 30,000 upon submission of original bill.

storage devices etc., which is study specific.)	
Archival of Documents at end of study (to be archived for 15 years):	1,50,000 One Lac Fifty Thousand (This amount will be paid at the end of the study)

4. INSITITIONAL OVERHEADS	
Institutional Overhead Charges:	25% on component 1 (per subject compensation based on actual visits completed). This is not applicable on components 2 (medical management and compensation of trial related injuries, and component 3 (additional costs).

The Parties agree that payments made for this Study per appendix B will be made to the SMO. AstraZeneca will make the payment to the SMO upon receipt of duly signed invoice for the study related activities per appendix B from the investigator/institution. The services provided by the SMO (payee) to the investigator/institution for this study are governed by a separate agreement between the SMO and investigator/institution that includes the financial obligations between those parties as well. AstraZeneca is not and will not be a party to the agreement between SMO and investigator/institution. AstraZeneca's only responsibility is to make payment per appendix B of this agreement to the SMO on the basis of the invoices raised by the investigator/institution. Investigator and institution release AstraZeneca from any financial obligations and/or disputes that arise in between SMO and investigator/institution concerning this study.

5. PAYMENT TERMS

Payments will be made to: **Payee Name: Ardent Clinical Research Services**

Account details:
Bank Name: HDFC
Bank Branch: Hingre Khurd Pune
PAN: APQPD7018M
Account No: 50200007013912
ISFC: HDFC0000825

All invoices should be clearly marked with the "D" code for the Study, and Subject. "E" code wherever applicable.

Invoices to be sent electronically to Or by post to: **AstraZeneca Pharma India Ltd**
Central Mail Room
Block N1, 12th Floor, Manyata Embassy Business Park,

Rachenahalli, Outer Ring Road,
Bangalore – 560045, Karnataka, India
T: + 91 80 67748000

Time for payments:	The Research Grants, the patient travel expenses and the reimbursements will be paid within a month (30 days) of receipt of a Invoice issued by the Institution or the Principal Investigator (starting from the date of site initiation till Close Out Visit has been performed) against the patients recruited and the visits, relevant activity has been completed. No payment will be made before the Principal Investigator has signed the protocol and before all authorisations required to proceed with the study have been obtained including approval of the relevant ethics committee. Payment is only due if the Principal Investigator/institution has fulfilled his/her obligations under this contract

APPENDIX C- FACILITIES, RECORDS and RESOURCES

1. PLANNED SUBJECT ENROLMENT

Number of enrolled subjects:	Approximately 30 subjects
Number of randomised subjects:	Approximately 15 subjects
First Subject enrolled by:	First Subject to be enrolled within 60 days from Investigator's receipt of written approval by Sponsor
Last Subject completed before/ LSLV:	Planned date 05 December 2019

2. MATERIALS PROVIDED BY COMPANY

Equipment:	ePRO devices (TrialMaxSlate®) to be provided by CRF Health and to be returned to CRF Health by study closure
Other materials:	Lab kits provided by Central lab Covance

3. MATERIALS PROVIDED BY STUDY SITE

Equipment: Calibrated weighing balance, height scale, sphygmomanometer, Centrifuge for samples, -20 freezer for samples, 12-lead ECG machine.

Other materials:

- A computer with high speed internet connection
- An on-line fax machine equipped with archive proof papers (if archive proof papers are not available, fax reports from the Central Laboratory and IVRS/IWRS reports/alerts should be copied)
- Scales for weight and height measurements
- Standard pulse and blood pressure measurement device
- Thermometer
- Thermometer for min./max. temperature monitoring in the rooms where Investigational Products will be stored/ Pharmacy.
- Local lab supplies for safety laboratory assessments such as dipsticks for urinalysis, vacutainers, etc.
- Power bar (for ePRO charging)
- Wi-Fi or good cellular phone signal (for ePRO transmitting)
- Stationary Items like Patient files, plastic sleeves,

papers for printing etc.,

4. SOURCE DATA, RECORDS AND STORAGE

4.1. Web-based Data Capture ('WBDC') and Electronic Patient Reported Outcome ('ePRO') System

Company may require the completion of a technical site assessment survey to determine that the computer and its associated hardware are technically capable for use in a Web-based Data Capture Study.

To meet key milestones and ensure integrity and completeness of study data, each Subject data should be entered into the electronic Case Report Form within 72 hours of each completed visit. Data queries shall be reviewed and responded to within 72 hours. Timelines for data entry and responses to queries may be shorter when the Study approaches an interim analysis or Data Base Lock. Data related to SAEs/AEs and/or Endpoints must be reported as defined in the Clinical Study Protocol.

4.1.1 WBDC, ePRO and/or other system access controls

Access to electronic systems used in the study will be strictly restricted to these (Study Site Staff, Company employees, Company data management centre staff, Subjects depending on the system) who have been appropriately trained. Each user will be allocated access to the system for their sole use only. Principal Investigator and/or his Study Site Staff understand that access codes/tokens and passwords are for personal use only and not to be shared with others, and that an electronic signature, when used, is the legally binding equivalent of a traditional handwritten signature.

4.1.2 ePRO training of Subjects

Principal Investigator and/or Study Site Staff are responsible for training Subjects on how to use the ePRO device, using the materials and training provided by the ePRO vendor.

4.1.3 Back-up procedures for system unavailability

ePRO; If the network is down, and the data has been saved on the ePRO device the data is stored on the device until next time data is sent.

WBDC; Back-up procedures for WBDC according to the Protocol.

4.2. Records and Documents

4.2.1 Medical Records

The medical (hospital/practice) records for each Subject should contain information which is important for the Subject's safety and continued care and to fulfil the requirement that critical Study data should be verifiable. To achieve this, the medical records of each Subject should clearly describe at least:

- that the Subject is participating in the Study, eg, by including the enrolment and/or the randomisation code and the Study code or other Study identification
- the Subject's general practitioner/family doctor was informed of the Subject's Study participation/was not informed and why
- date when Informed Consent was obtained
- diseases (past and current; both the disease studied and others, as relevant)
- treatments withdrawn/withheld due to participation in the Study
- treatments given, including Investigational Product, changes in treatments during the Study, and the time points for the changes.
- visits to the clinic during the Study, including those for Study purposes only
- Serious Adverse Events (if any) including causality assessments
- date of and reason for discontinuation; and
- additional information according to local regulations and practice.

Company will have the right to assess the validity of the electronic system used for medical records in order to ensure proper Source Data Verification ('SDV').

4.2.2 Case Report Form as source document

The following variables may be directly recorded in the CRF and need not be present in Subject medical records (electronic/paper CRF = source document), provided that data is recorded in the CRF at once. Please specify in this section or add an annex where source data is listed.

- Ethnic group and race
- Criteria of SAE met or not
- AstraZeneca aware of SAE
- Reason of concomitant medication
- Date and results of local laboratory reports

- The laboratory reports received via fax/e-mail from the Central Laboratory should be signed and dated by the Principal Investigator or delegate and should be filed in the Investigator's Study File (ISF).
- Reports from the IWRS/IVRS (faxed or e-mail-printouts) will be considered as source data and should be filed in the ISF.
- ECG printouts or duplicates, should be signed and dated by the Investigator or delegate
- Biological sample logs provided by AstraZeneca.

4.2.3 Electronic Patient Reported Outcome Source Data

Sites are responsible for ensuring that patients complete the correct assessments at the correct time. Sites are responsible for managing the device and selecting subject identifier (E-code) on the device which corresponds to the patient who is completing the assessment.

The ePRO source data are recorded electronically in a central database hosted by the ePRO service provider and are available for review and maintenance during the Study. Principal Investigator maintains control of the data and must authorise all ePRO data changes.

4.3. Storage of Study Documents

The Study Documentation shall be retained and stored during the Study and for 15 years after Study Closure in accordance with this Agreement.

When a WBDC/ ePRO system is used for the Study, Company will provide Principal Investigator with copies of the Study Site's electronic Case Report Forms, ePRO and associated data on an optical media eg, Compact Disc ('CD') or digital versatile disc ('DVD'). The media should be regarded as part of the Investigator's study file, but may be stored separately.

4.4. Emergency Unblinding Tools

Treatment codes are accessible according to the Protocol.

ADDENDUM TO CLINICAL STUDY AGREEMENT
("Addendum 1")

This Addendum to Financial Agreement ("**Agreement**") is executed as of this the 19th day of Jan 2017 ("**Effective Date**") by and between:

1 **PREAMBLE AND INTENTION**

The Parties are,

1. **Sun Pharma Advanced Research Company Ltd.** (CINL73100GJ2006PLC047837),a company registered under the Companies Act, 1956 having its registered office at SPARC Ltd, Akota Road, Akota, Vadodara – 390020 India and having a business address at 17/B, Mahakali Caves Road, Andheri East, Mumbai 400093, India, which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the **"Sponsor"**).

AND

2. **Mahatma Gandhi Mission's Medical College &Hospital** ,a hospital having its registered office at N-6 CIDCO, Aurangabad-431 003, Maharashtra, India, which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the **"Institution").**

AND

3. **Dr. Chandrashekhar Tamane**, MBBS, MD (Oncology), Principal Investigator, at Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad-431 003, Maharashtra, India (hereinafter referred as the **"Investigator")**

(Each a "Party" and collectively, the "Parties")

WHEREAS:

1.1 The Parties entered into a Clinical Study Agreement dated **9th day of August 2016** (the "**Agreement**").

1.2 The Parties wish to amend and supplement certain of the terms and conditions of the Agreement as recorded herein ("**Addendum 1**").

1.3 This addendum is prepared to outline the financial grant section for the Hospitalization, Local Laboratory, and Chemoport/Central line expenses in accordance with the current legislations in India; and incorporate certain changes in the Schedule A.

1.4 This Addendum 1 forms part of and is to be read with the Agreement as from the date of the last signature hereof ("**Effective Date**")

2 **AMENDMENTS**

The Parties hereby amend the Agreement as recorded in **Schedule A** hereto.

3 GENERAL

3.1 As of the Effective Date, this Addendum 1 shall be read together with and shall be deemed to be incorporated in the Agreement and shall be governed by the terms, conditions and definitions set forth in the Agreement, as if such terms were fully set forth herein.

3.2 Except as expressly amended hereby, the terms and conditions of the Agreement shall continue in full force and effect and are hereby confirmed and ratified.

3.3 If there is inconsistency between the provisions of the Agreement and this Addendum 1, the provisions of this Addendum 1 shall prevail.

4 SIGNATORIES

Sun Pharma Advanced Research Company Ltd.

Signature: Ajay Singh Solanki

Name: **Mr Ajay Singh Solanki**

Designation: **Sr.GM, Clinical Operations**

Date: 21. Jan. 2017

Place: **Mumbai**

Mahatma Gandhi Mission's Medical College & Hospital

Signature:

Name: **Dr. Rajendra Bohra**

Designation: **Dean**

Date: 01 Feb 2017

Place: Aurangabad

Mahatma Gandhi Mission's Medical College &Hospital

Signature:

Name: **Dr. Chandrashekhar Tamane**

Designation: **Principal Investigator**

Date: 01 Feb 2017

Place: Aurangabad

KS

MGM's Medical College * Aurangabad *

APPROVED BY LEGAL
No.: R15.19.01.17
INITIALS

SCHEDULE A

AMENDMENTS TO THE AGREEMENT

Financial Grant

Protocol No.: CLR_16_13

Protocol Title: "A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer."

Investigator's Name: Dr. Chandrashekhar Tamane

Institute Name: Mahatma Gandhi Mission's Medical College & Hospital

Heads	Amount in INR mentioned in Executed CSA Version 01	Amount in INR with breakup	Schedule
Local laboratory charges **Haematology** (Haemoglobin, TLC, DLC, ANC, Platelets) **Clinical chemistry** Liver function tests (AST, ALT, AP, total bilirubin, serum albumin) Renal function tests (BUN/urea, serum creatinine) Electrolytes (serum Na+, K+, Cl-) **ECG**	As per actual	**Haematology:** Rs 240 **Clinical Chemistry:** Rs 540+Rs 350+ Rs 420 **Total: Rs 1550** **ECG:** Rs 300	**Monthly**
Hospitalization charges (Per Day)	As per actual	Rs 2950	**Monthly**
Central line/Chemoport charges	Not Mentioned	**Chemoport charges-** 40,000 **Central Line charges:** Rs. 5000	**Monthly**

1) All invoices will be addressed to: Mr. Ashok Gupta, Sun Pharma Advanced Research Company Ltd., Clinical Research Dept, 17/B,Mahal industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai 400093, Maharashtra, India.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name:Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement is made by and between the following four parties:

1)ACCUTEST: Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	**2) PRINCIPAL INVESTIGATOR:** Name: Dr. Ashish Ramchandra Deshmukh Address: Skin and VD Department, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad, Maharashtra, India - 431003. Tel.: 0240-6601100 Ext- 316 Fax: +91 2772-246108 Email ID: ashish7557@gmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**
3) INSTITUTE: Name of the Authorized Signatory:Mr. Rajendra Bohra Designation: Dean Name of the Institute:MGM Medical college and Hospital. Address: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad, Maharashtra, India – 431003 Tel.: 0240-6601100 Fax: 91 2772-246108 Email ID: rajbohra@msn.com **Hereinafter "INSTITUTE."**	**4) SITE MANAGEMENT ORGANISATION** Name of Authorized Signatory: Dr. Sushil Chaudhary Designation: Director Address:.Grapecity Research Solutions LLP Prakash Housing Society, Block no-D/2, Thergaon, Pune- 411033, Maharashtra, INDIA, Tel.: 020-65222284 Fax: 020-65222284 Email ID: sushilrc.chaudhary@gmail.com

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

This Clinical Trial Agreement is effective from the date of last signature("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "A Randomized, Double-Blind, Placebo-Controlled, three arm, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence and Safety of Tacrolimus Ointment, 0.1% (Encube Ethicals Private Limited) with Protopic® (tacrolimus) ointment, 0.1% (Astellas Pharma US, Inc.) in the Treatment of Moderate to Severe Atopic Dermatitis "("the Protocol") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number:ARL/CT/18/002
Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authorities' authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

Section 1: Study Protocol
The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. Inthecase of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

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(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

The Principal Investigatorhereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

In the event the Principal Investigatorbecomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigatorshall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigatorto the pertinent ethics committee.

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2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature, significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in theICH-GCP and Schedule Y.ThePrincipal Investigator should obtain written Informed consent fromthepatient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteriaprior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;
- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

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The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **25 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrollment period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additionalsubjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the PrincipalInvestigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover, the Principal Investigatorshallupdate/maintain the investigator study file provided at the time of Site Initiation Visit (SIV)andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;

b) Investigator's Brochure and updates (If applicable);

c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;

d) Notifications/Approval of regulatory authorities;

e) CVs and signature sheet for key study personnel (e.g. investigators);

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f) Approved and signed informed consent forms;
g) CRFs/eCRFs (investigator's copy) (If applicable);
h) Serious adverse events documentation and related correspondence/reporting;
i) Instructions for handling of Study Drug;
j) Screening, enrollment, and monitoring logs and subject identification code list;
k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

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The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. All persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event thatAccutest or authorities perform an audit, the Institute,PrincipalInvestigatorwill allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutestto be present. The Principal Investigatorshall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

When, for reasons ofthefulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

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Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintainthesecrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requestedforby the ethics committee responsible for approvingthe Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutestor their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutestprior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement.ThePrincipal Investigator hereby transfers and assigns to Accutestthe Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained duringtheperformance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to alldata obtained in the Study in

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perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigatorshall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor hisemployees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Propertyin perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigatorwarrant, by the execution of this Agreement, that they have not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL&Sponsorto encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL &Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

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(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

Section 5: Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator.

5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the investigator site file documents.

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient, he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study.In the event that the Study is terminated with the consent of Accutest,the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, provided that:

a) one month after shipment of the Study material, no subjectshavebeen enrolled or the Principal Investigator recruits no subjectsor recruits such a low number of subjectsthat it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,

d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

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e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs(blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the conduct of the Study;

c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

It shall be the Principal Investigator's/ Institute's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation, those which relate to the Principal Investigator, the Institute, and its employees and/or collaborators.

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjectsrecruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

Inthecase of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event thatAccutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that:

- where a subjecthasbeen recruited to the Study in violation of the Protocol, there shall be no obligation of payment;

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- where failure by a subjectto complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment;
- where failure by a subjectto complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject'sdropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator;

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subjectinvolvedin accordance with the Protocol.

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its

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insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered byAccutestand any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates, directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b)the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India;

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study;

(e) Principal Investigator's material deviation from the Protocol;

(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

ThePrincipalInvestigatorwarrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study.

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

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(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments, or other conveyances of rights or interests in real, personal or intellectual property ofAccutest or relating to the Study Drug;

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutestor of other entities having a financial interest in the Study Drug; and

(d) All other financial interests, payments, and other compensation.

During the conduct of the Study and for one (1) year after its completion, the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigatorshall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind.

The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The Institute and the Principal Investigator will not receive any benefits from the conduct of the Study beyond the remuneration agreed herein.

8.3 Assignment

Principal Investigator shall not assign his rights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The Institute and the Principal Investigator understand and agree that this Agreement is being entered into to perform services for Accutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) Pvt. LTD. NAVI MUMBAI

M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

The Institute/Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Accutest. Any such consent shall not relieve the Institute and/or the Principal Investigator of its obligations hereunder.

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement.Correspondences shall be made to the following addresses:

1)ACCUTEST: Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	**2) PRINCIPAL INVESTIGATOR:** Name: Dr. Ashish Deshmukh Address: Skin and VD Department, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad, Maharashtra, India - 431003. Tel.: 0240-6601100 Ext- 316 Fax: +91 2772-246108 Email ID: ashish7557@gmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**
3) INSTITUTE: Name of the Institute: MGM Medical college and Hospital. Address: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad, Maharashtra, India – 431003 Tel.: 0240-6601100 Fax: +91 2772-246108 Email ID: rajbohra@msn.com **Hereinafter "INSTITUTE."**	**4) SITE MANAGEMENT ORGANISATION** Name of Authorized Signatory: Dr. Sushil Chaudhary Designation: Director Address:.Grapecity Research Solutions LLP Prakash Housing Society, Block no-D/2, Thergaon, Pune- 411033, Maharashtra, INDIA, Tel.: 020-65222284 Fax: 020-65222284 Email ID: sushilrc.chaudhary@gmail.com

Section 10: Contractual

10.1 Entire Agreement

This Agreement (including the Protocol and the APPENDIX) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by all parties and refers to this Agreement.

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. NAVI MUMBAI

M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Mumbai, India will have sole jurisdiction over the litigation

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

Section 11: Miscellaneous

Principal Investigator/Instituteherebyconfirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B.To have received a copy of the Investigator's Brochure and to be informed of its contents.

The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date	**2) PRINCIPAL INVESTIGATOR:** Signature and Date

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. MUMBAI

M.G.M. Hospital Aurangabad.

INICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

Mr. Rajendra Talele, Head- Clinical Development Services 19 Oct 2018	**Name: Dr. Ashish Deshmukh** Ashish 01/11/2018
3) INSTITUTE: For MGM Medical College and Hospital Signature and Date 1/11/18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

APPENDIX I

Financial Support for Investigator:

(a) Total payment, compliance, completed patients, inclusion Criteria:

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and application regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) PVT LTD. THANE-MUMBAI

M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

(b) Payments will be made based upon the completed CRF/eCRFscollected by Accutest

(Please refer Appendix II for payment detail).

(c) Pro rata temporis payment

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) Protocol violators, exclusion

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) Income tax

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA – for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories. Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Grapecity Research Solutions LLP
PAN number: AAPFG8186L
GST Number: 27AAPFG8186L1ZH

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. MUMBAI

M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement.
2. All local investigations (local lab tests, radiological scans,any diagnostic assessments etc.) are included in PI grants
3. All Services provided by the site under this Agreement are taxable under the laws related to Goods & Service tax in India (GST) and it is required to be charged at the rate of 18%, as may be amended from time to time. The Sponsor / CRO (applicable word as per agreement should be used) undertakes to provide Patient Visit Tracker on monthly basis (on last day of the month) to CRCs for the trial and on the basis of the tracker site shall raise invoice for the month. The invoice shall be in accordance with the terms of Rule 5 of the Tax Invoice, Debit and Credit Notes Rules of Goods & Service Rules 2017.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 19.07.2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date Ashish 01/11/2018 **Name: Dr. Ashish Deshmukh**
3) INSTITUTE: For MGM Medical College and Hospital Signature and Date 1-11-18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

M.G.M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

APPENDIX II

Visit	**Amount (INR)**
Visit 1 Screening	10000
Visit 2 Baseline	7000
Visit 3 Interim Visit	7000
Visit 4 End of study/ Early Termination	7000
Safety Follow	5260
Total PI Grant (a)	36260
Institutional overhead (10%) (b)	3626
TOTAL (a+b)	**39886**
GST 18% (c)	3988.6
Grand Total (a+b+c)	**43874.6**
TOTAL PI GRANT	**43880**

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 43880/-** per completed patient (including institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, radiological scans, any diagnostic assessments etc.) are included in total PI grants

The above payment also includes following charges:

a) Investigator(s) and other team members fees
b) Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.
c) Patient recruitment
d) Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction
e) Data Clarification Form (DCF) resolution
f) Consultation charges
g) Document archival

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paid on production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 5000/- for 6 screen failure patients (which includes all laboratory investigation charges) against 25 completed patients will be reimbursed.
6. Expense towards themedical management of serious adverse events will be made as per actual.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor.
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed by the patient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Accutest. Accutest will generally provide procedural material required by the protocol for the study. However, in the event Sponsor and Accutest requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) Accutest will pay a sum for every complete and evaluable patient.

b) A complete and evaluable patient is defined as follows:

- All procedures must be performed according to the protocol
- A patient will only be included according to the inclusion/exclusion criteria
- All data are documented completely and accurately

c) All payments will be on a pro rata basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit, then an equivalent amount mentioned in the above budget will be deducted.

d) An invoice will be generated/ requested for payment on a monthly basis according to the actual work performed (after source data verification and CRF/eCRFs review for completed visits). An invoice will be generated/ requested according to days completed by the patient

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

as specified above. The credit period of releasing the payment will be two months after receiving invoice.

e) If the patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without a waiver, if applicable), then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in the budget as mentioned. The TDS will not be deducted on payment released for patient compensation.

g) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

h) If the trial terminates prematurely, any payments made by Accutest exceeding the amount earned will be promptly refunded to Accutest (minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be done on the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generate a monthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 19-Oct-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date 01/11/2018 **Name: Dr. Ashish Deshmukh**
3) INSTITUTE: For MGM Medical college and Hospital Signature and Date 1/11/18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
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ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. MUMBAI

M. G. M. Hospital Aurangabad.

महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ TY 763139

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००३
4 SEP 2018
सक्षम अधिकारी

श्रीमती. पी. एस. तळकर

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this 19 day of NOV 2018 by and between

Dr Mahendra Suryawanshi MBBS, MS (Surgery), at MGM Medical College and Hospital, N-6, CIDCO Aurangabad 431003 Maharashtra, India (hereinafter referred to as the "Principal Investigator" or "PI")

AND

MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 Maharashtra, India.

AND

Macleods Pharmaceuticals Limited, a company incorporated under the Companies Act, 1956 having its registered Office at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai - 400059, India and include its successors and assignees (hereinafter referred to as "Macleods") in connection with conduct of clinical trial

AND

Orapecity Research Solution LLP, Prakash Housing Society, Block no-D/2, Thergaon, Pune- 411033, Maharashtra, India.

Protocol Number: CT-189-ENZO(F)-2015

Protocol Title:

"A Multicentric, Open label, Randomized, Comparative, Clinical Study evaluating Safety and Efficacy of Fixed Dose Combination of Trypsin 48 mg + Bromelain 90 mg + Rutoside Trihydrate 100 mg enteric coated tablet versus Serratiopeptidase 10 mg enteric coated tablet in patients for healing potential in surgical wounds after minor surgery."

PI and Macleods and other party (If applicable like Institute/ Hospital etc) hereinafter are individually referred to as **"the Party"** and are jointly referred to as **"the Parties"**.

WHEREAS:

1. Macleods Pharmaceuticals Ltd. is a pharmaceutical company having R&D centre in Mumbai and has necessary infrastructure and facilities to provide such services of clinical trial and in turn desires to engage the services of the PI to conduct/assist in such a trial;
2. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

1. Provision of Services

1.1 The services to be provided by the PI to Macleods Pharmaceuticals Ltd. are described in detail in the statement attached here to and incorporated herein by references as **Exhibit B** (hereinafter referred to as **"the Proposal"**).

1.2 The PI will conduct various activities in respect of Clinical Trial (hereinafter referred to as **"activities"**) in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B**)
- All applicable International Council for Harmonization (ICH) Good Clinical Practice (hereinafter referred to as **"GCP"**) guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.
- Activities will be carried out as specified in **Exhibit A** and Protocol of Clinical trial as amended from time to time.

1.3 Macleods Pharmaceuticals Ltd. will provide the PI with all the information, documents, and materials which, in Macleods Pharmaceuticals Ltd.' reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.4 Macleods Pharmaceuticals Ltd. transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.5 Macleods Pharmaceuticals Ltd. will appoint a representative (hereinafter referred to as the "Clinical Research Associate (CRA)" to be authorized to monitor the activities of the Clinical Trial. The CRA will coordinate performance of Clinical Trial with the PI. All communications between Macleods Pharmaceuticals Ltd. and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CTM. Macleods Pharmaceuticals Ltd. may, at its discretion, change the CRA during the course of Clinical Trial and inform the PI accordingly.

1.6 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Macleods Pharmaceuticals Ltd.

2.0 Payment

2.1 The total fees and expenses payable by Macleods Pharmaceuticals Ltd. to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B**.

2.2 Macleods Pharmaceuticals Ltd. shall pay the PI for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

2.3 Payment shall be made by account payee cheque / DD only.

3.0 Term

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

4.0 Termination and Consequences of Termination

Termination:

4.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

4.2 Either Party may terminate this Agreement by written notice of forty five (45) days to the other Party without assigning any reason thereof and **with no penalty on either side.**

4.3 Either Party may terminate this Agreement by written notice of thirty (30) days in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

4.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 4.3 above.

4.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

4.6 Upon expiry or termination of this Agreement, Macleods Pharmaceuticals Ltd. shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Macleods Pharmaceuticals Ltd. to the PI under this Agreement exceed the project costs as set forth in the study Budget.

4.7 Upon expiry or termination of this Agreement, the PI shall, at Macleods Pharmaceuticals Ltd.' option, either immediately transfer to Macleods Pharmaceuticals Ltd. or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

5. Intellectual Property Ownership, Invention & Discoveries and Publication

5.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Macleods Pharmaceuticals Ltd. which is disclosed to the PI is and shall always remain the sole and exclusive property of Macleods Pharmaceuticals Ltd.

5.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Macleods Pharmaceuticals Ltd. However, the PI may publish data generated at their (own) site:

- Only upon getting written approval from Macleods Pharmaceuticals Ltd. and
- Only after the first publication of such data by the Macleods Pharmaceuticals Ltd.

6.0 Representations; Indemnification

6.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and

to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws

The PI will be covered by a professional indemnity of sufficient value as decided by Macleods Pharmaceuticals Ltd., which shall be in force through out the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

7.0 Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of India.

8.0 Arbitration

8.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be Mumbai.

9.0 Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force Majeure shall be provided to the other Party.

10.0 Record Keeping & Retention:

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction. PI need to archive all the study related documents after study completion as per the regulations and Macleods Pharmaceuticals Ltd. requirements

11.0 Review of Work, Audit

11.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Macleods Pharmaceuticals Ltd. Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Macleods Pharmaceuticals Ltd.

12.0 Headings

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

13. Notices & Service of documents

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Macleods Pharmaceuticals Ltd. shall be addressed to:

Macleods Pharmaceuticals Ltd.
Clinical Trials Department,
R & D III, Plot no. 18, Road no-09, Marol MIDC,
Andheri (East), Mumbai 400 093.
Telephone No.: 91-22-61132900
Fax No.: 91-22-28304641

All the correspondence/ notices to be sent by Macleods Pharmaceuticals Ltd. to PI shall be addressed to:

Dr Mahendra Suryawanshi,
MBBS, MS (Surgery),
MGM Medical College and Hospital, N-6, CIDCO,
Aurangabad-431003 Maharashtra, India.
Contact details: 8087401054

Investigator		
Name: Dr Mahendra Suryawanshi **MBBS, MS (Surgery),** **Designation:** Principal Investigator **Site Address:** MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 Maharashtra, India	Signature	Date 24/11/18
Witness By		
Name: P Chaitanya Kiran **Designation:** MBBS, D(MS) RESIDENT	Signature	Date 24/11/18
MGM Medical College and Hospital		
Name: Dr. Rajendra Bohra **Designation:** Dean **Site Address:** MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 Maharashtra, India	Signature	Date 24/11/18
Witness By		
Name: Jayesh V. Kakde **Designation:** Clinical Research Coordinator	Signature	Date 24/11/18
Grapecity Research Solution LLP		
Name: Dr Sushil Chaudhary **Designation:** Director Grapecity Research Solution LLP	Signature	Date
Witness By		
Name: **Designation:**	Signature	Date
Macleods Pharmaceuticals Ltd.		
Name: Dr Ashish Mungantiwar **Designation:** Head – Clinical Trials Macleods Pharmaceuticals Ltd.	Signature	Date 19/11/18
Witness By		
Name: Priyanka. Shrivastava **Designation:** Team Leader – Clinical Trial dept	Signature	Date 19/11/18

Exhibit A

Responsibilities of PI: Dr Mahendra Suryawanshi

INVESTIGATOR AGREEMENT FOR THE CLINICAL TRIAL

Protocol Number: CT-189-ENZO(F)-2015

Protocol Title:

"A Multicentric, Open label, Randomized, Comparative, Clinical Study evaluating Safety and Efficacy of Fixed Dose Combination of Trypsin 48 mg + Bromelain 90 mg + Rutoside Trihydrate 100 mg enteric coated tablet versus Serratiopeptidase 10 mg enteric coated tablet in patients for healing potential in surgical wounds after minor surgery."

1. I have sufficient time, adequate staff, and appropriate facilities to conduct and complete the Clinical Study. I agree to make these resources available for the duration of the study and agree that other Studies will not divert essential subjects or facilities away from this trial.

2. I assure Macleods Pharmaceuticals Ltd., that no other Clinical Study conducted by me shall give rise to a conflict of interest or interfere with the Clinical Trial.

3. I will endeavor to ensure an adequate recruitment rate during the clinical investigation.

4. Macleods Pharmaceuticals Ltd. will furnish me with copies of the Investigator's Brochure and the Study Plan or Protocol and I agree:
   a) to become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the preclinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and
   b) to become well acquainted with the Study Plan before signing it.

5. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the Study.

6. I understand that I shall have primary responsibility for the accuracy, legibility, and security of all Study data, documents, and subject records both during and after the Study. I will be responsible for signing the Case Report Forms (CRFs). Any alteration of the raw/source data shall be signed and dated, without obliterating the original entry.

7. I agree to abide by the following conditions governing my handling of the data associated with this Study.

a) I am required to maintain adequate records regarding all investigational product received and used by me including batch numbers, dates, and quantities. If the study is terminated, suspended, discontinued, or completed, I shall return to Macleods Pharmaceuticals Ltd., any unused supplies unless other arrangements are made by Macleods Pharmaceuticals Ltd.

b) I am required to prepare and maintain adequate and accurate subject's case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the Clinical Study.

c) I understand I am to furnish my records of the Study to Macleods Pharmaceuticals Ltd.

d) I will maintain records of the disposition of the investigational product and other records for the duration as per current regulation and Macleods Pharmaceuticals Ltd. requirement. To avoid any possible errors I will contact Macleods Pharmaceuticals Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e) I agree to provide accurate information to the Ethics Committee upon request. I also agree to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies'

authorities and ethical obligations, as set forth below:

1. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, I will make records related to the Clinical Study available for inspection and copying.
2. The subject's identity will not be released except under the following limited circumstances.
   Where data verification procedures demand inspection of subject's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person.
3. The subject's identity shall not be released to third parties without the subject's or subject's legal representative's prior consent. Accordingly, the study subject's or subject's legal representative's consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

8. I agree to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Macleods Pharmaceuticals Ltd.

9. I shall not commence the Study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the subject or the Subject's legal representative.
   I shall provide the Ethics Committee or Institutional Review Board with all required information.

10. I certify that the investigational products for clinical investigation will be provided only to subjects under my personal supervision or under the supervision of the following sub-investigators). I further certify that the investigational products will not be supplied by me to any investigator, other than those listed above as sub-investigators, or to any clinic, medical facility, or study site for use.

11. No procedure will be performed until all site personnel have been properly trained.

12. I agree to be responsible for the personal safety and well being of the subjects. To this end, I agree to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:
   Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature:
   a) I will ensure that subject / subject's legal representative or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the subject / subject's legal representative
      The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.
   b) I will ensure that the subject / subject's legal representatives are given the opportunity to inquire about the details of the Clinical Study. The information given to the subject / subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the Clinical Study at any time without any sanction. I will make an effort to ascertain the reasons for any withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.
   c) I will ensure that the subject / subject's legal representatives are provided adequate time to decide whether or not they wish to participate / wish their ward to participate in this clinical investigation.

13. I will discuss with Macleods Pharmaceuticals Ltd. any question of modification of the study plan and obtain Macleods Pharmaceuticals Ltd written agreement and also approval from the ethics committee prior to implementation of any modification. I will not precede with a non-emergency deviation from the Clinical

Protocol without approval from Macleods Pharmaceuticals Ltd. and as needed the Ethics Committee. It is my responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Macleods Pharmaceuticals Ltd. including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

14. I will report all adverse events/ serious adverse events to Macleods Pharmaceuticals Ltd.

a. I will promptly report:

- Deviations from or changes to the protocol to eliminate immediate hazards to the study patients.
- Changes increasing the risk to patients and/or affecting significantly the conduct of the study.
- All adverse drug reactions (ADRs) and Adverse Events (AEs) those are both serious and unexpected.
- New information that may affect adversely the safety of the subjects or the conduct of the study.

b. All staff in contact with the subject should be aware of their responsibility to note and report all adverse events reported by the Subjects / subject's legally acceptable representative.

c. The Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Macleods Pharmaceuticals Ltd. within 24 hours except for those SAEs that the protocol or other document (e.g. Investigator's brochure) identifies as not requiring immediate reporting.

e. The immediate reports should be followed promptly by detailed written reports including the completed SAE Forms.

f. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the study subjects rather than by the subjects' names, personal identification numbers and/or addresses.

g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Macleods Pharmaceuticals Ltd. according to the reporting requirements and within the time periods specified by Macleods Pharmaceuticals Ltd. in the Protocol.

h. I will personally be responsible for, or will appoint a sub-investigator to be responsible for all study related medical decisions.

15. I will report all deviations from the protocol to Macleods Pharmaceuticals Ltd. and the study monitor.

16. I will notify Macleods Pharmaceuticals Ltd., immediately, about withdrawal of approval by the reviewing Ethics Committee of my part of the Clinical Study.

17. I will comply with any request by Macleods Pharmaceuticals Ltd. to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. PI understands that Macleods Pharmaceuticals Ltd. is required by law to discontinue shipments of investigational product to me if I fail to comply with the Study Protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

18. I agree to permit personnel from Macleods Pharmaceuticals Ltd. and/or the Study Monitor/ auditor to visit me and/or the Study Site to monitor my compliance with the protocol and/or audit the investigational records. To facilitate Macleods Pharmaceuticals Ltd. or the Study Monitor's audit, I further agree to make records related to the Clinical Study available for inspection and copying.

19. I agree to maintain confidentiality regarding all information generated in the course of this Clinical Study. I further agree to ensure that the confidentiality of all information about subjects and the information supplied by Macleods Pharmaceuticals Ltd. is respected by all persons, with the limitations discussed above.

20. I agree to submit and sign a Final Report of the Clinical Study within three months after termination o completion of the Clinical Study or of my part in the Clinical Study to the Ethics Committee.

I agree to abide by this investigator Agreement.

Investigator Signature: _____

Date : 04/11/2018

Exhibit B: Proposal (Budget)

Budget and Payment Terms

Protocol Number: CT-189-ENZO(F)-2015

Protocol Title: "A Multicentric, Open label, Randomized, Comparative, Clinical Study evaluating Safety and Efficacy of Fixed Dose Combination of Trypsin 48 mg + Bromelain 90 mg + Rutoside Trihydrate 100 mg enteric coated tablet versus Serratiopeptidase 10 mg enteric coated tablet in patients for healing potential in surgical wounds after minor surgery."

Name of PI: Dr Mahendra Suryawanshi

1. All payments would be made only upon fulfillment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Amount per subject will be paid to PI according to the following payment schedule.
   Budget per completed subjects: Rs.6000/- including all the taxes and institutional overhead charges.
   Lab charges (as per actual for the lab investigations as per protocol) – Rs. 3000/- per patient for all the lab investigations as per the protocol at Visit 1 and Visit 3. Any other fees (EC fees, as per actual).
   Travel reimbursement of Rs. 200/- will be given to the subject at each of Visit 1 (If patient is randomized), Visit 2 and Visit 3, provided site is maintaining proper documentation of the travel reimbursements given to the subject.

3. Expected Number of subjects: Planned number of patients to be enrolled from site: 48 (The number of patients can be increased depending on the overall recruitment status of the trial & potential of the patient pool at the site after discussion with Macleod's Pharmaceuticals Ltd.)

4. The following deductions will be made, if applicable:
   - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
   - Any capital expenses for the site incurred by Macleods Pharmaceuticals Ltd. on behalf of PI will be deducted from the fee payable to PI.

5. **Payee Details:**

TYPE OF PAYMENT	PAYEE NAME	PAN NUMBER
For Investigator Fee	Grapecity Research Solution LLP	AAPFG8186L
For EC Fee	MGM Medical college	AAATM4256E
For Lab investigations	Grapecity Research Solution LLP	AAPFG8186L

Investigator		
Name: Dr Mahendra Suryawanshi **MBBS, MS (Surgery),** **Designation:** Principal Investigator **Site Address:** MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 Maharashtra, India	Signature	Date 24/11/18
Witness By		
Name: P. Chaitanya Kiran Designation: MBBS, DNB Resident	Signature	Date 24/11/18
MGM Medical College and Hospital		
Name: Dr. Rajendra Bohra Designation: Dean **Site Address:** MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 Maharashtra, India	Signature	Date 24/11/18
Witness By		
Name: Jayesh V. Kakde. Designation: Clinical Research Coordinator	Signature	Date 24/11/18
Grapecity Research Solution LLP		
Name: Dr Sushil Chaudhary Designation: Director Grapecity Research Solution, LLP	Signature	Date
Witness By		
Name: Designation:	Signature	Date
Macleods Pharmaceuticals Ltd.		
Name: Dr Ashish Munganiwar Designation: Head – Clinical Trials Macleods Pharmaceuticals Ltd.	Signature	Date 19/11/18
Witness By		
Name: Priyanka Shrivastava Designation: Team Leader - Clinical Trial dept.	Signature	Date 19/11/18

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TR 792496

DIST. TREASURY THANE

जिल्हा कोषागार कार्यालय, ठाणे
20 JUL 2018
मुद्रांक प्रमुख लिपीक / लिपीक

PRODUCT CODE:	**Sotagliflozin/SAR439954**
STUDY CODE:	**EFC14875**
STUDY NAME:	**THE SCORED TRIAL**

INVESTIGATOR/INSTITUTION/SMO CONTRACT

Site Name & City: MGM Medical College and Hospital, Aurangabad

Study Code/ Name: EFC14875 / The SCORED Trial

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

This Contract (hereinafter "the Contract") is made on this **30th day of August 2018,** by and among:

DOCTOR PRASHANT UDGIRE, Principal Investigator, having his address at Department of Cardiology, MGM Medical College and Hospital, N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA

Hereinafter the "**INVESTIGATOR**",

AND

MGM MEDICAL COLLEGE AND HOSPITAL, having its address at N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA represented for the purposes hereof by Dr. Rajendra B. Bohra, Dean

Hereinafter the "**INSTITUTION**"

AND

ARDENT CLINICAL RESEARCH SERVICES a private Site Management Organization, having its registered office at 318, Level-3, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, *India* represented for the purposes hereof by Chandu Devanpally, Managing Director,

Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function" (hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin/SAR439954** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled "The SCORED Trial, EFC14875" and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care;

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Cardiology, and

WHEREAS, the SMO is a site management organization which is taking care of site management activities for studies of the INVESTIGATOR and is responsible for clinical trials/clinical activities/coordination etc. at the INSTITUTION and has accordingly provided the Sponsor a certificate, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS the SPONSOR shall have no liability whatsoever arising out of selection and appointment of SMO and payments made to the SMO, including but not limited to any claims, demands, actions, causes of action, judgments, damages, expenses and costs,

including attorney's fees, which arise out of, result from, occur during or are connected in any manner with the Study or any related activities or Investigator meetings, irrespective of whether or not they are sponsored, supervised or controlled by the SPONSOR, except such liability arising directly and solely from gross negligence on the part of the SPONSOR, and

WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **MGM Medical College and Hospital having its address at N-6 CIDCO, Aurangabad, Maharashtra-431003, India** (hereafter the «Study Site»). The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as

well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR, the INSTITUTION and the SMO agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 4. TERM.

This Contract is being entered into force from 17 September 2018 ("the Effective Date") and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately **51 (Fifty One) months** from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (Thirty) Subjects** (the «Subjects »), within approximately **15 (Fifteen) months**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall

only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary Subject information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION, the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION, the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files

should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR, the INSTITUTION or the SMO is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR, the INSTITUTION or the SMO to the SPONSOR.

17.4 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

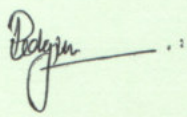
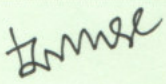
22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between

them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**DR. PRASHANT UDGIRE**
[Title]	**Clinical Study Unit Director**	**[Title]**	**Principal Investigator**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**Y. J. Cama**	**[Name]**	Dr. Deepak S. Bhosle

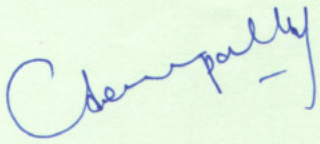
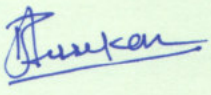
MGM MEDICAL COLLEGE AND HOSPITAL (INSTITUTION)		**ARDENT CLINICAL RESEARCH SERVICES (SMO)**	
[Signature]		**[Signature]**	
[Name]	**Dr. Rajendra B. Bohra**	**[Name]**	**Mr. Chandu Devanpally**
[Title]	**Dean**	**[Title]**	**Managing Director**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	Dr. Rajesh D. Kadam	**[Name]**	Mrs. Pranjali Aurkar

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 17 September 2018

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

   Such amount is divided as follows:

EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees (Rs.)**	**Site Coordinator Fees* (Rs.)**	**Subject reimbursement (for travel, meals during site visit)(Rs.)**
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500

EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees (Rs.)**	**Site Coordinator Fees* (Rs.)**	**Subject reimbursement (for travel, meals during site visit)(Rs.)**
Close-out visit	14,900	3,100	1,500
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the Subjects. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during Subject's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 20% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) SPONSOR will pay one time lump sum of Rs.75,000/- (Rupees Seventy Five Thousand only) after the Study Closure to the PAYEE for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

9) A onetime non-refundable start-up fee of Rs.50,000/- (Rupees Fifty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, Subject identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

10) All the payments for the study will be as per the break-up mentioned in **Annexure 1**.

11) All the devices or instruments provided by the SPONSOR will be returned to SPONSOR at the time of closeout.

12) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

13) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION/PAYEE on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

1) **For payments related to INSTITUTION:**

Bank Name & Branch:	IDBI Bank, New Osmanpura,
Bank IFSC	IBKL0000376
Account No.:	0376104000000107
PAYEE:	MGM Medical College
PAN No.:	AAATM4256E
GST No.:	27AAATM4256E1ZP

2) **For payments related to SMO:**

Bank Name & Branch:	HDFC Bank, B.T. Kawade Road, Ghorapadi, Pune
Bank IFSC	HDFC0003708
Account No.:	50200007013912
PAYEE:	Ardent Clinical Research Services
PAN No.:	APQPD7081M
GST No.:	27APQPD7081M1Z9

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

Annexure 1

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100-Ext.423, Fax: 0240-2487727, web: www.mgmmcha.org

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CONFIRM that, Ardent Clinical Research Services is taking care of site management activities of my studies at our centre who is going to manage clinical trials/ clinical activities/coordination at MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, INDIA. For the services being provided by the Ardent Clinical Research Services, the budget will be made as follows:

The breakup of the budget is as follows:

1. 65 % grant of total PI fees paid to hospital/Institution
2. 35 % grant of total PI fees paid to SMO
3. Institutional Overhead 20 % paid to hospital/Institution
4. 100 % grant of CRC fees paid to SMO
5. Archival fees will be paid to hospital/Institution
6. Study start up payment paid to SMO
7. Subject travel reimbursement paid to SMO
8. SAE reimbursement, Lab tests cost and others on actual paid to hospital/Institution

Thanking you,

12/8/2018

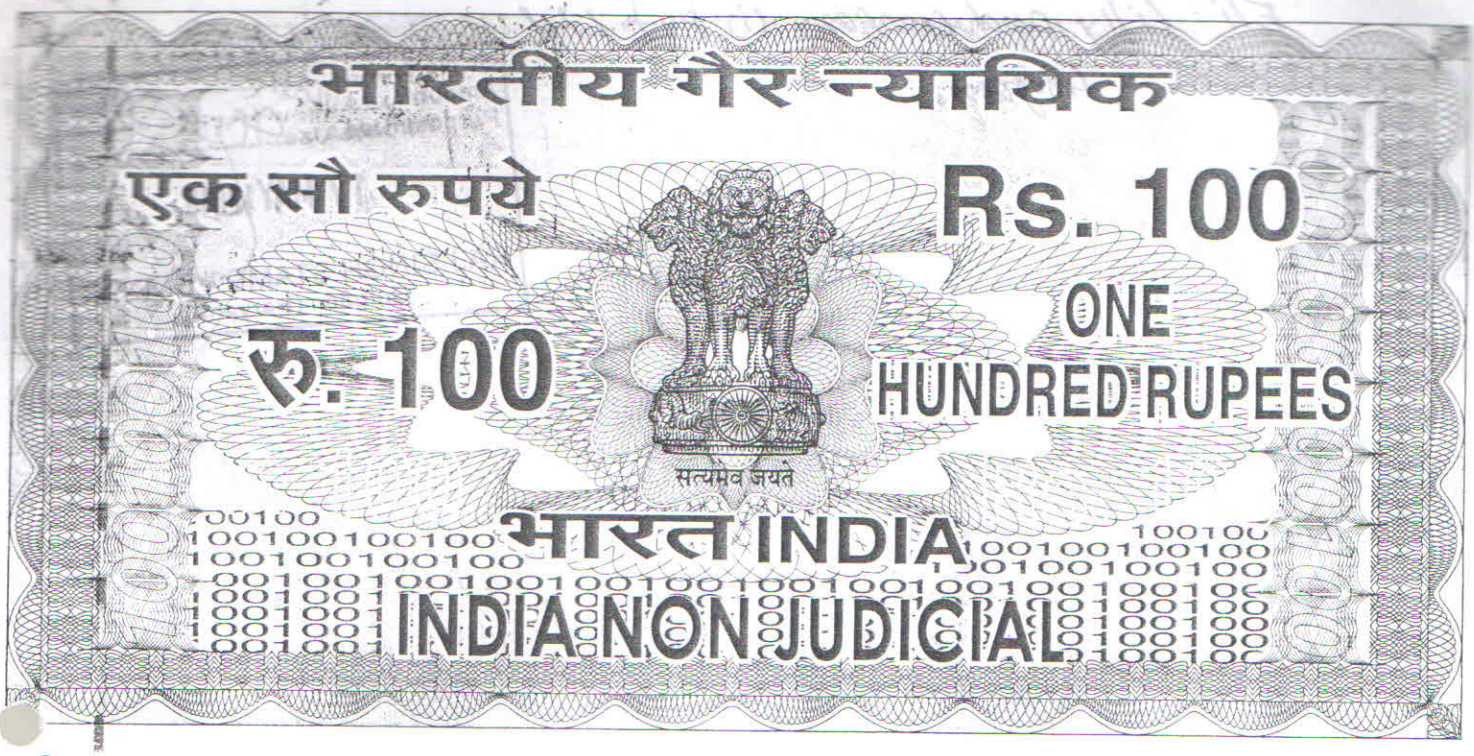
Dr. Prashant Prabhakar Udgire
(Principal Investigator)
MBBS MD (Medicine) DM Cardiology
MGM Medical College and Hospital, N-6, CIDCO,
Aurangabad-431 003, Maharashtra, INDIA
DR. PRASHANT P. UDGIRE
M.D. (Medicine), D.M.(Cardiology) Mumbai
Asst. Prof. & Interventional Cardiologist
MGM Medical College & MCRI
Aurangabad-431003
Reg. No 2002/03/

Dr. Deepak Bhosle

12/8/2018

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.
Dr. Deepak Bhosle
[Head of Department]
MBBS MD Diabetologist
MGM Medical College &
Hospital, N-6 cidco, A'bad
Maharashtra, India

Page 1 of 1



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OUS LOA
Revised: 07 2017

17-May-2018

Dr. Hemangi Jerajani
Professor and Head, Department of Dermatology
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kamothe
Navi Mumbai - 410209

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Dear Jerajani:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd.("Lilly"), **AND Dr. Hemangi Jerajani,** Professor and Head of Department of Dermatology, as the principal investigator ("Investigator"), of **MGM Institute of Health Sciences, 3rd Floor, Sector 1, Kamothe, Navi Mumbai - 410209** ("Institution") for the performance of the study ("Study) entitled "Phase 3 Multicenter, Double-Blind Study to Evaluate theLong-Term Safety and Efficacy of Baricitinib in Adult Patients with Atopic Dermatitis" protocol **I4V-MC-JAHN** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an independent contractor of Institution with privileges to use Institution's facilities and resources. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study
Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if

Eli Lilly and company (i) Pvt Ltd
Gurgaon

2615

Sr No.....
Amount.....
Purpose/Use.....

17 MAY 2018

RAJ SINGH STAMP VENDOR
Gurgaon (Haryana)

applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); and all other applicable national, state and local laws, regulations and standards. Investigator and Institution shall ensure that all of sub investigators, associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution'sStudy Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws,

regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of the facility or processes related to the StudyLilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection.Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be retained to meet such requirements. The Investigator and/or Institution agree to take the appropriate measures to prevent premature destruction of essential documents.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order. Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study. Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above.

E. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

F. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly.

G. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-

4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations. Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

I. Contract Research Organization Involvement

Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

J. Equipment

Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institutionagree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

K. Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;

(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committeesor national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee

Payment in connection with the Study will be made to the name and address listed below:

Payee: MGM Institute of Health Sciences

Address:MGM Institute of Health Sciences

3rd Floor, College Building, Sector 1, Kamothe, Navi Mumbai - 410209

PAN: AACTM0014C
(Identification Number for Tax Purposes)

B. Payment Schedule

In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institutionwill receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by **30-Dec-2020**, unless Lilly givesInvestigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional patients.Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to

the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigatorthat the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution.

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institutionagree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any paymentsexceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. INDEMNIFICATION

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or

expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement.

IV. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement.

V. INDEPENDENT CONTRACTOR

Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

By signing this Agreement, Investigator and Institution represent and warrant thatthey have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institutionin connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Haryana Jurisdiction).

If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by courier service to **Saurabh Sharma, Eli Lilly and Company, Plot No. 92, Sector – 32, Gurgaon, Haryana - 122001**, If You have any questions, please call **Saurabh Sharma** at **+91-9891614224.**

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.

(Signature of Authorized Official)

Dr. Rajeev SharanShrivastava
Associate Director –Regulatory Affairs and Pharmacovigilance

(Typed or Printed Name and Title)

17 MAY- 2018

(Date)

AGREED AND ACCEPTED:
Investigator

H. R. Jerajani

Dr. Hemangi Jerajani

Professor & Head, Department of Dermatology
MGM Medical College, Navi Mumbai
(PI on behalf of MGMIHS.

(Date) 22-05-2018

AGREED AND ACCEPTED:
Registrar
MGM Institute of Health Sciences
Sector-1, Kamothe, Navi Mumbai

(Signature of Authorized Official)

Dr. Rajesh B Goel, Registrar

(Typed or Printed Name and Title)

22.05.2018

(Date)

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Exhibit A:JAHN

S. No.	Investigations	No of Visits	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principle Investigator Fee:** @Rs. 4000/- per patient clinic visit x 17 visits for 10 enrolled patients **(Z)**	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	4000	680,000
2.	**Co-Investigator Fee:** @ Rs. 2500/- patient clinic visit x 17 visits for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	2500	425,000
3.	**Study Coordinator Fee:** @ Rs. 1500/- per patient clinic visit x 17 visits for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1500	255,000
4.	**Phlebotomist Fee** @ Rs. 700/- per patient clinic visit x 12 visits for 10 enrolled patients	Total-12 visits (Visits-1, 2, 3, 4, 5, 6, 8, 11, 13, 15, 16/ED, 801)	700	84,000
5.	**Patient Inconvenience** including TDS @ Rs. 1111/- per patient x 17 clinic visits x 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1111	188,870
6.	**Institutional Grant** 20% of PI+ Co-I + SC fees	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1600	272,000
7.	**Admin grant** @ Rs. 235 per visitx 9 clinic visits x 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	235	39,950
8.	Initial Admin Grant paid after Site initiation visit		30,000	30,000
9.	Final Admin Grant paid after data base lock		30,000	30,000
			Total Grant for 10 Patients	**20,04,820**

Exhibit B: Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
Total Payment for each visit inclusive of 20% institutional Grant on PI, Co-I, CRC fees		
1.	Visit 1*	11,646
2.	Visit 2	11,646
3.	Visit 3	11,646
4.	Visit 4	11,646
5.	Visit 5	11,646
6.	Visit 6	11,646
7.	Visit 7	10,946
8.	Visit 8	11,646
9.	Visit 9	10,946
10.	Visit 10	10,946
11.	Visit 11	11,646
12.	Visit 12	10,946
13.	Visit 13	11,646
14.	Visit 14	10,946
15.	Visit 15	11,646
16.	Visit 16 or Early Discontinuation	11,646
17.	Visit 801	11,646

*Visit 1 can occur 0 to 56 days from last visit of JAHL study and will be paid if V1 occurs separate from V8 in JAHL study. For the majority of patients, Visit 1 will also be the last visit of JAHL study; thus any assessments/procedures conducted during the final visit in JAHL study should not be repeated during first visit for Study JAHN.

Exhibit C: Procedural Payments

S. No	Procedure at Local Lab	Visit	Cost of Procedure	Total Amount for 10 pts
1.	**Urine Pregnancy test** @ Rs.300/- x 17 visit for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	300	51,000
2.	Reimbursement of locally-sourced over-the-counter emollients (up to 500g). Price is per bottle/Tube and requires third-party receipts to be provided.			On Actuals

Descriptions:

- Per Patient budget excluding GST: **INR 2,00,482**
- Site enrollment target (Z): **10 patients**
- Total Budget for 10 patients including procedural payments:**INR20,55,820**
- Total Budget, including GST: **INR 24,25,868**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received on or before 5th of every month
- All the visits and procedures included in the invoice must be entered into CRF (Case Report Form) for the payment to be processed

Procedural Payment:

- Procedural payments will be processed and reimbursed on request from the site.
- The procedures performed at site's internal laboratory will be reimbursed based on amount specified in this agreement. A copy of invoice for the procedure is needed in this case.
- The procedures performed at External laboratory will be reimbursed based on amount claimed in invoice. A copy of invoice for the procedure is mandatory in this case.

GST:

- The above mentioned calculation of visit payment does not include GST. GST will be paid as applicable based on the invoices received
- **Eli Lilly India PAN number: AAACE8901F**

Patient Reimbursement

- Patient reimbursement amount is inclusive of the TDS amount.

Screen Failure & Early Discontinuation Patients:

- This LOA is valid for a maximum of 10 Randomized patients.
- Early Discontinuation fee will be paid if all required procedures as per schedule of events in study protocol have been carried out at a clinic visit by the patient.

Kindly note that if final number of patient visits/ lab tests is more or less, addition or deduction respectively would be made to the above grant heads at the rates given against each.

हरियाणा HARYANA

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Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

OUS Templates
OUS LOA
Revised: 07 2017

17-May-2018

Dr. Hemangi Jerajani
Professor and Head, Department of Dermatology
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kamothe
Navi Mumbai - 410209

Dear Jerajani:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd.("Lilly"), **AND Dr. Hemangi Jerajani,** Professor and Head, Department of Dermatology, as the principal investigator ("Investigator"), **of MGM Institute of Health Sciences, 3rd Floor, Sector 1, Kamothe, Navi Mumbai - 410209** ("Institution") for the performance of the study ("Study) entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis," protocol **I4V-MC-JAHL** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an independent contractor of Institution with privileges to use Institution's facilities and resources. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); and all other applicable national, state and local laws, regulations and standards. Investigator and Institution shall ensure that all of sub investigators, associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution'sStudy Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of the facility or processes related to the StudyLilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection.Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be

retained to meet such requirements. The Investigator and/or Institution agree to take the appropriate measures to prevent premature destruction of essential documents.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order.Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study.Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above.

E. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

F. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly.

G. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations.Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

I. Contract Research Organization Involvement

Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

J. Equipment

Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institutionagree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

K. Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;
(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committeesor national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee
Payment in connection with the Study will be made to the name and address listed below:

Payee: MGM Institute of Health Sciences

Address:MGM Institute of Health Sciences

3rd Floor, College Building, Sector 1, Kamothe, Navi Mumbai - 410209

PAN: AACTM0014C
(Identification Number for Tax Purposes)

B. Payment Schedule
In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institutionwill receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by **30-Dec-2018**, unless Lilly givesInvestigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional

patients.Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement.It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigatorthat the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution.

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institutionagree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any paymentsexceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. INDEMNIFICATION

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain

counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement.

IV. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement.

V. INDEPENDENT CONTRACTOR

Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

By signing this Agreement, Investigator and Institution represent and warrant thatthey have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institutionin connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Haryana Jurisdiction).

Exhibit A:JAHL

S. No.	Investigations	No of Visits	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principle Investigator Fee:** @Rs. 4000/- per patient clinic visit x 9 visits for 10 enrolled patients **(Z)**	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	4000	360,000
2.	**Co-Investigator Fee:** @ Rs. 2500/- patient clinic visit x 9 visits for 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	2500	225,000
3.	**Study Coordinator Fee:** @ Rs. 1500/- per patient clinic visit x 9 visits for 10 enrolled patients	Total 9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1500	135,000
4.	**Phlebotomist Fee** @ Rs. 700/- per patient clinic visit x 7 visits for 10 enrolled patients	Total 7 Visits (Visits-1, 2, 5, 6, 7, 8/ED, 801)	700	49,000
5.	**Patient Inconvenience** including TDS @ Rs. 1111/- per patient x 9 clinic visits x10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1111	99,990
6.	**Institutional Grant** 20% of PI+ Co-I + SC fees	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1600	144,000
7.	**Admin grant** @ Rs. 444 per visit x 9 clinic visits x 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	444	39,960
8.	**Chest X-Ray** @ Rs.300/- x 1 visit for 10 enrolled patients	Visit 1	300	3,000
9.	**12-lead ECG** (performed and read locally) @ INR 300/-per patient on visit 1 for 10 enrolled patients	Visit 1	300	3,000
10.	Initial Admin Grant paid after Site initiation visit		30,000	30,000
11.	Final Admin Grant paid after data base lock		30,000	30,000
			Total Grant for 10 Patients	**11,18,950**
12.	Screen Failure Cost (Assume 10 pts)	Visit 1	12,455	1,24,550
13.	Pre-Screening Reimbursement @ INR 1000 per identified patient in pre-screening log for upto 30 patients		1000	30,000

Exhibit B: Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
Total Payment for each visit inclusive of 20% institutional Grant on PI, Co-I, CRC fees		
1.	Visit 1 & Screen Failures	12,455
2.	Visit 2	11,855
3.	Visit 3	11,155
4.	Visit 4	11,155
5.	Visit 5	11,855
6.	Visit 6	11,855
7.	Visit 7	11,855
8.	Visit 8	11,855
9.	Visit 801	11,855
10.	Early discontinuation Visit	11,855

Exhibit C: Procedural Payments

S. No.	Procedure at Local Lab	Visit	Cost of Procedure	Total Amount for 10 pts
1.	**Urine Pregnancy test** @ Rs.300/- x 7 visit for 10 enrolled patients	Total-7 visits (Visit 2, 4, 5,6,7,8,801)	300	21,000
2.	Herpes Zoster Vaccine, provided & administered locally by Site, if required. Up to one vaccine administration per patient			On Actuals
3.	Reimbursement of locally-sourced over-the-counter emollients (up to 500g). Price is per bottle/Tube and requires third-party receipts to be provided.			On Actuals
4.	**Purified PPD TB test** @ Rs.300/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	300	3,000
5.	**QuantiFERON®-TB Gold test** @ Rs.4000/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	4000	40,000

Descriptions:

- Per Patient budget excluding GST: **INR 1,11,895**
- Site enrollment target (Z): **10 patients**
- Total Budget including Pre-screened patients, Screen failure patients& Procedural Payments:**INR13,37,500**
- Total Budget, including GST: **INR 15,78,250**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received on or before 5th of every month
- All the visits and procedures included in the invoice must be entered into CRF (Case Report Form) for the payment to be processed
- Payments for Pre-screening will be processed based on the pre-screening logs received from site on weekly basis.

Procedural Payment:

- Procedural payments will be processed and reimbursed on request from the site.
- The procedures performed at site's internal laboratory will be reimbursed based on amount specified in this agreement. A copy of invoice for the procedure is needed in this case.
- The procedures performed at External laboratory will be reimbursed based on amount claimed in invoice. A copy of invoice for the procedure is mandatory in this case.

GST:

- The above mentioned calculation of visit payment does not include GST. GST will be paid as applicable based on the invoices received
- **Eli Lilly India PAN number: AAACE8901F**

Screen Failure Patients:

- The Payment of screen failure patients would be paid on the basis of patients who have signed the ICF and the eCRF data entry for the same has been completed in Electronic Data Management System (INFORM) and as per amount specified for screen failure in Exhibit A (Visit 1).

Patient Reimbursement

- Patient reimbursement amount is inclusive of the TDS amount.

Screen Failure & Early Discontinuation Patients:

- This LOA is valid for a maximum of 30 pre-screened, 10 screen failures & 10 Randomized patients.
- Early Discontinuation fee will be paid if all required procedures as per schedule of events in study protocol have been carried out at a clinic visit by the patient.

Pre-Screening Reimbursement:

- To commence after site has received Ethics Committee approval and this Letter of agreement is fully signed & executed.
- Payable upon weekly receipt of completed Pre-screening Log, for identified subjects based on I/E criteria.
- Frequency of payment will be Monthly.

Kindly note that if final number of patient visits/ lab tests is more or less, addition or deduction respectively would be made to the above grant heads at the rates given against each.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA28597914835081R
Certificate Issued Date	:	16-Jan-2019 12:12 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0891483231626659R
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	MGM MEDICAL COLLEGE AND HOSPITAL
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARAHALLI SOUHARDA CREDIT CO OPERATIVE LTD

Please write or type below this line

MGM's Medical College

Statutory Alert:

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India, (the "**Institution**"), and
- Dr. Bhosale Deepak Sadashiv , Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India (the "**Investigator**"), and
- IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited), having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road, Bangalore – 560103, Karnataka, India ("**IQVIA**"),

Each a "**Party**" and together the "**Parties**".

Protocol Number:	CT/P015/CMR/16/03_01
Protocol Title:	A Phase III Randomized, Double Blind, Parallel Group, Placebo Controlled, Multi-centre, Multinational Study to Evaluate Efficacy and Safety of TRC150094 as an Add On to Standard of Care in Improving Cardiovascular Risk in Subjects with Diabetes, Dyslipidemia and Hypertension
Protocol Date:	17 Jul 2017
Sponsor:	Torrent Pharmaceuticals Limited
Country where Site is Conducting Study	India
Investigator:	Dr. Bhosale Deepak Sadashiv
Key Date:	**100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrolment Date" below)**
IRB/IEC	Contact name: Dr. Manvendra Kachole (Chairperson) - +91 9225930400

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or **CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or **GCPs**: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favoured charity); and/or benefits to third persons related to government officials (e.g., close family members).

Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

Informed Consent: consent obtained from a Study Subject that complies with guidelines established by the Declaration of Helsinki, International Conference of Harmonization (ICH), and all the applicable laws, guidelines, or standards, governing the participation of Study Subject in trials.

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA' services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Investigator has represented that he/she has the requisite expertise and resources for providing clinical trial and research services, and other services for the pharmaceutical industry;

WHEREAS, the Institution has represented that it has the necessary infrastructure and resources to carry out clinical trial services.

WHEREAS, the Institution and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, terms and conditions of the approval of the Independent Ethics Committee ("**IEC**"), any and all applicable local, national and international laws, regulations and guidelines, acceptable ethical and medical considerations, including in particular, but without limitation, GCPs and MCI Regulations and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

The Investigator shall ensure that neither administration of the Investigational Product to any Study Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Study Subject until it is satisfied that all relevant regulatory and IEC approvals have been obtained

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject and same shall be maintained by the Investigator for record.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards and will also be kept confidential under the terms of Section 3 of this Agreement; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

The Investigator shall ensure that the clinical samples required to be tested during the course of the Study are tested in accordance with the Protocol and at a laboratory approved by the Sponsor/ IQVIA.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

In the event the Sponsor or IQVIA reasonably believes there has been any research misconduct in relation to the Study at the Site, Institution and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator shall be responsible for obtaining and maintaining all the approvals from the relevant IEC for the conduct of the Study at the Institution. The Investigator is also responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labelling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Investigator shall ensure that the clinical samples required to be tested during the course of the Study are tested in accordance with the Protocol and at a laboratory approved by the Sponsor.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA

Investigator hereby warrants that:

a) Investigator has the necessary expertise to perform the Study. Investigator shall at all time keep Sponsor indemnified against any acts and or omissions from the Investigator.

b) Investigator is free to participate in the Study and there are no rights which may be exercised or by obligations owed to any third party which might prevent his performance of the obligations detailed in this Agreement.

c) Investigator is not involved in any regulatory or misconduct litigation or investigation by the food and drug authorities, the medicines and healthcare products regulatory agency, or other regulatory authorities in India or outside India which can affect the validity or any other way adversely affect the services provided under this Agreement. No report/ study produced by him/her in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

d) Investigator has considered and is satisfied that facilities to the Study are available to him/her at the Institution and that he/she is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable Investigator to perform the Study efficiently and in accordance with his/her obligations under the Agreement.

e) Investigator carries out professional liability insurance (or the Institution carries professional liability insurance) for Study Subjects on such terms and conditions as required by the relevant rules and regulations applying for the performance of clinical studies and details and evidence of the coverage shall be provided to Sponsor and, on the Sponsor's request, to the competent ethics commission before commencement of the Study.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations. The Investigator shall be responsible for collating adverse events and including such data in the Study database.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding of which they become aware that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified in the Protocol and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials (if any) provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment B hereto. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA s or Sponsor with respect to such facility improvements.

1.7. Enrolment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrolment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrolment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/ IQVIA has the right to limit enrolment at any time.

If IQVIA requests Site's attendance at a Study start up meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made by IQVIA in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

3. CONFIDENTIALITY

3.1 Definition

"**Confidential Information**" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrolment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator or Institution or any of its personnel;
(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
(iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall:

(i) have access to the Confidential Information on a need to know basis;

(ii) Not use Confidential Information for any purpose other than the performance of the Study; or
(iii) Not disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:
(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
(iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure
In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction
Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival
This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property
Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions
For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions
Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

5.1.1 The Sponsor agrees that Institution and Investigator shall be permitted to publish or present the results subject to this clause and any publication policy described in the Protocol, provided that such policy does not obstruct publication unreasonably. If it is a multi-centre trial, any publication based on result obtained at Institution (or a group of Trial Sites) shall not be made before the first multicentre publication unless otherwise agreed. If a publication concerns the analysis of subject data from a multi-centre clinical trial the publication shall make reference to relevant multi-centre publication(s).

5.1.2 Up on completion of the Study, and any prior publication of multi centre data, or when the Study Data is adequate (in Sponsor's reasonable judgement), the Investigator and Institute may prepare the data derived from the Study for publication. Such data will be submitted to the Sponsor for review and comment prior to publication. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for a review at least thirty (30) days prior to submission for publication, public dissemination, or review by publication committee.

5.1.3 Institution and Investigator agree that all reasonable comments made by the Sponsor in relation to a proposed publication will be incorporated into the publication.
During the period for a review of proposed publication in clause 5.1.2 above, the Sponsor shall be entitled to make reasoned request to the Institution and Investigator that publication be delayed for a period of three (3) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information/or intellectual rights and knowhow and Institute and Investigator shall not unreasonably withhold its consent to such request The Investigator, Institution as well as the SMO shall not issue a press release that references any Protocol or Study conducted by Sponsor, or that uses Sponsor's name or trademarks.

5.2 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("**Unpublished Data**") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.3 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.4 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication, promotion or news/press release without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance

with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.5 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Study Team Member Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to potential Dual Capacity conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, IQVIA, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;
(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials; and
(vi) anti-corruption compliance.

Names of members of Study Staff may be processed in IQVIA" study contacts database for study-related purposes only.

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions. The Investigator shall indemnify Sponsor against any claims arising from any breach by the Investigator or the Institution or the SMO of this Clause.

6.3 Data Controller

The Sponsor shall be the data controller for such personal data except that, if IQVIA deals with any personal data under this Agreement in the manner of a data controller, IQVIA shall be the data controller of such personal data to the extent of such dealings.

IQVIA may process "**personal data**", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "**Data Protection Legislation**"), of the Investigator and Study Staff for study-related purposes and all such processing will be carried out in accordance with the Data Protection Legislation.

6.4 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7. STUDY SUBJECT INJURY

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:
(a) failure by Institution, Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
(b) negligence or wilful misconduct by Institution, Investigator or any of their respective personnel, or
(c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, wilful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. INDEMNITY

9.1 The Investigator shall indemnify Sponsor, its directors, officers, and employees (hereinafter collectively "**Sponsor Representatives**") for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third party (including the relevant regulatory/statutory authority and government/semi-government bodies) claim, action or proceeding or otherwise arising from the following :

(a) Investigator's negligence, malpractice, misconduct, improper acts or omissions of the Investigator and/or the employees or agents of the Investigator in the performance of Investigator's obligations hereunder or the instructions of the Sponsor;
(b) Non adherence or breach of any applicable law or non-compliance in accordance with the Agreement;
(c) deviation from the Protocol;
(d) unauthorized use of IMP.

9.2 Sponsor shall indemnify the Institution and its directors, trustees, authorized representatives and employees including the staff (collectively the Indemnitees) for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third party (including the relevant regulatory/statutory authority and government/semi-government bodies) claim, action or proceeding or otherwise arising by reason of personal injury, including death, to any person caused by or allegedly caused by the investigational medicinal product used in the Study, except where such claim has arisen from events mentioned in clause 9.1 (a) to 9.1 (d).

10. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages, except as stated below.

This Section 10 "Consequential Damages" shall survive termination or expiration of this Agreement.

11. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 11 "Debarment" shall survive termination or expiration of this Agreement.

12. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.

Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 12 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

13. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

14. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence

any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

15. INDEPENDENT CONTRACTORS

The Investigator and Institution and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

16. TERM & TERMINATION

16.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever is later (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

16.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately without any onus or additional remuneration upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be

jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrolment.

16.3 Consequences of Termination

In the event this Agreement is prematurely or orderly terminated, Site shall provide IQVIA with all Study data including any work product, final result report and CRF in relation to the Study relating to the period from the commencement of the Study until termination of the Agreement. The Investigator reserves a right to retain one copy of all the material as the result of the Services performed, which will remain subject to the confidentiality provisions herein, and to be used only if a dispute arises regarding the Services performed by the Investigator hereunder.

17. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered
(a) in person,
(b) by certified mail, postage prepaid, return receipt requested,
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Name: Dr. Deepa Joshi, Vice President, Discovery Research & Clinical Development Address: Torrent Research & Development Centre, Ahmedabad-Gandhinagar Highway, Bhat P.O., Gandhinagar, Gujarat - 382 428 Tel: +91 079 23969100
To IQVIA	Name: Kapil Jhawar Sr. Clinical Project Manager Address: IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited)having its office at B-101-106, Shapath IV, Opp. Karnavati Club, S G Road, Ahmedabad- 380 051, India
To Institution	Name: Mahatma Gandhi Mission's Medical College and Hospital
To Investigator	Name: Dr. Bhosale Deepak Sadashiv Address: Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India

18. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert

its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

19. MISCELLANEOUS

19.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

Any change in the terms of this Agreement shall be valid only if the changes are made in writing, agreed and signed by the Parties.

19.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

19.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer or subcontract any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

19.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.
Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

19.5 Applicable Law and Dispute Resolution

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

Any dispute arising out of or in connection with this Agreement will be finally settled through courts of the state or province in which the Site, is located.

19.6 Survival:

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED (FORMERLY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED):

By: Tanuka Ganguly

Title: Director, Site and Patient Networks

Signature: Tanuka Ganguly

Date: 17/Jan/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Bhosale Deepak Sadashiv

Title: Principal Investigator

Signature: _____

Date: 21/Jan/2019

ACKNOWLEDGED AND AGREED BY Mahatma Gandhi Mission's Medical College and Hospital
By: Dr. Rajendra Bohra

Title: DEAN

Signature: _____ 21/01/2019

Date: _____

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

PAYMENT TERMS

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	MGM Medical College
Payee Address	Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra, India
Email Address	mgmmca@themgmgroup.com
Bank Name	IDBI Bank
Bank Account IBAN Number or branch number	0376104000000
IFSC Code	IBKL0000376
GST Registration Number	Not Applicable
VAT/GST/Tax ID Number	Pan Number: AAATM4256E
PAYMENT METHOD	Electronic Fund Transfer

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing. The parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERM

IQVIA will pay the Payee monthly (or every three (3) months), on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior month (or prior 3 months) enrolment data confirmed by subject CRFs received from the Site and data verification supporting subject visitation

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility

Subject to the provisions of the following paragraph, neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site.

IQVIA is obligated to, and will withhold tax, as applicable, in accordance with Country Name tax laws, as amended from time to time.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to the Investigator, the Institution and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Good and Services tax ("**GST**") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

D. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

E. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited), Bangalore
Attn: **Finance PSC – Accounts Payable (Investigator Payments)**
Address:
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number, Investigator name, Site number and Payee GST registration number. Upon receipt and verification of the invoices, reimbursement for invoices will be included with the next regularly scheduled payment.

F. **EC/IRB/IEC** FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of appropriate documentation.

G. **H. MEETING ATTENDANCE: [IF SITE'S ATTENDANCE IS NOT REQUIRED AT A STUDY MEETING, BE SURE IT'S STATED EXPLICITLY]** Necessary travel and lodging expenses (including meals) incurred by the Site when attending Study start up meetings or other meetings necessary to provide information regarding the Study or Investigational Product will be reimbursed on a pass-through basis upon receipt of supporting invoices from a third party vendor.

- **RECORD STORAGE FEE**
  A record storage payment will be made to Site at the completion of the Study subject to receipt of a document storage quotation and upon Sponsor/CRO approval. The record storage fee will not be provided in the event where a third party vendor has been contracted by Sponsor to perform record storage.

  In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

- **SCREENING FAILURE**

  Reimbursement for screen failures will not exceed Five (5) screen failure(s) paid per One (1) subject randomized.

  To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All payments for this Study in accordance with the attached budget will be paid by IQVIA by wire transfer.

H. **MINIMUM ENROLMENT GOAL**

Site acknowledges that Site's minimum enrolment goal is **30** subjects and that Site will use best efforts to reach the enrolment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

I. **BUDGET TABLE**

VISIT	*AMOUNT (INR) (INCLUSIVE OF OVERHEAD 25%)
SCR	10315
D0	5416
W4	7898
W12	10257
W24	10257
W36	7898
W50	7712
FUP	8239
TOTAL COST PER PATIENT	**67992**

The cost per patient is inclusive of patient travel expense.

UNSCHEDULED VISIT PROCEDURES Unscheduled visits should only take place if there is an immediate risk to subject safety, or in the event that the additional visit is pre-approved by IQVIA in writing, and not to exceed 2 visits per subject per visit. To be eligible for reimbursement for unscheduled visits, completed CRF pages

must be submitted to IQVIA within 5 days of visit with any additional information which may be requested by IQVIA to appropriately document the subject visit.

PROCEDURES	AMOUNTS (Inclusive of Overhead 25%)
Patient Reimbursement, Expenses, Patient Travel - Per Visit	500
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these key components: A comprehensive history; A comprehensive physical examination; Vital signs, weight, height; Medical decision making of high complexity.	2297
Vital signs, weight, height	342
12-lead ECG: Includes tracing, interpretation and report	186
Combined: Blood Draw, venipuncture, phlebotomy specimen collection with lab handling and shipping; Simple	279
Collection of specimen; urine, urine collection	62
Ambulatory blood pressure monitoring, 24 hours or longer (AMBP) (ABPM); utilizing a system such as magnetic tape and/or computer disk: Includes recording, scanning analysis, interpretation and report	2359

ATTACHMENT B
EQUIPMENT (*optional*)

The Site will be supplied with/ by:
• Ambulatory Blood Pressure Monitoring machine (ABPM)

All materials and equipment provided ("Equipment") by the Sponsor or IQVIA /vendors contracted by the Sponsor shall remain the sole property of the Sponsor/ IQVIA /vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:
a) be subject to removal at any time upon the Sponsor's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;
b) be used only for the purposes of the Study;
c) be used in accordance with any manuals or instructions while in possession of the Site;
d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;
e) be clearly identified as the sole property of the Sponsor/ IQVIA /vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and
f) upon completion or termination of the Study, IQVIA, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the Sponsor or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable.

ATTACHMENT C
APPROVAL LETTER

Thane Bharat Sahakari Bank Ltd.
Main Branch,Naupada,Thane.

D-5/STP/(V)/C.R.1005/1/04/1905-07/04

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INDIA STAMP DUTY MAHARASHTRA

AMENDMENT #2 TO INVESTIGATOR CLINICAL TRIAL AGREEMENT

This Amendment #2 ("Amendment") to Clinical Study Agreement dated 27 Dec 2018 (the "Agreement"), effective as of the later of the dates appearing on the signature page, is entered into by and among, Dr. Pole Shivaji Marotrao ("Principal Investigator") at Mahatma Gandhi Missions Medical College and Hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra, India. ("INSTITUTION"), Ardent Clinical Research Services ("SMO") located at 318, Level-3, Cannaught place building, Next to Franklin, Bund garden road, Opposite Wadia College, Pune-411001, Maharashtra, India.**and SIRO Clinpharm Pvt. Ltd.,** a company incorporated under the laws of India whose principal place of business is located at SIRO Clinpharm Pvt. Ltd., Kalpataru Prime, 1st floor, Unit Nos. 3 & 4, Plot no. D-3, Road no. 16, Wagle Industrial Estate, Thane (W) - 400 604, Maharashtra, India. (hereinafter referred to as "SIRO").

PI, INSTITUTION, SMO and SIRO are hereinafter individually referred to as 'Party' and collectively as 'Parties'.

WHEREAS, the parties have entered into **Clinical Trial Agreement** (the "Agreement") dated **27 Dec 2018**.

AND WHEREAS, the parties desire to amend certain terms of the Agreement;

NOW THEREFORE, the parties agree as follows:

I. In the existing CTA on page no. 14 under the existing Schedule A budget and payment scheme the budget sheet as mentioned therein be deleted and updated with the following budget and read as hereunder:

Type of visit	Professional fees	Procedural fees	Patient Travel Reimbursement
	(INR)	(INR)	(INR)
Screening	₹ 3,000.00		₹ 500.00
First Study Procedure	₹ 35,000.00	₹ 35,000.00	₹ 500.00
Second study procedure (Optional as per PI discretion)			₹ 500.00
Final Follow Up Visit	₹ 5,000.00		₹ 500.00
Total (A)	₹ 43,000.00	₹ 35,000.00	₹ 2,000.00
Institutional Overhead (B=25% of A)	₹ 10,750.00	NA	NA
Total (A+B=C)	₹ 53,750.00	₹ 35,000.00	₹ 2,000.00
GST (D=18%)	₹ 9,675.00	₹ 6,300.00	₹ 360.00
Total	**₹ 63,425.00**	**₹ 41,300.00**	**₹ 2,360.00**
Total per subject	**₹ 1,07,085.00**		

For Thane Bharat Sahakari Bank Ltd.
Authorised Signatory

MOM's Medical College * Aurangabad

CLINPHARM PVT. LTD. THANE 400 604

All other terms and conditions of the Agreement shall remain in full force and effect.

Upon execution this **Amendment #2** shall form part of the Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in QUADRIPARTITE by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

Partha Chatterjee,

Signature
Designation - Head Clinical operations and CTS

Date: 07 MAR 2019.

INSTITUTION

Dr Rajendra Bohra

Signature
Designation - Dean

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Date: 18 MAR 2019

INVESTIGATOR

Dr. Pole Shivaji Marotrao

Signature
Designation: Principal Investigator

Date: 16 MAR 2019

SMO

Mr. Chandu Devanpally

Signature
Designation: Managing Director

Date: 15/03/2019

CLINPHARM
THANE
400 604