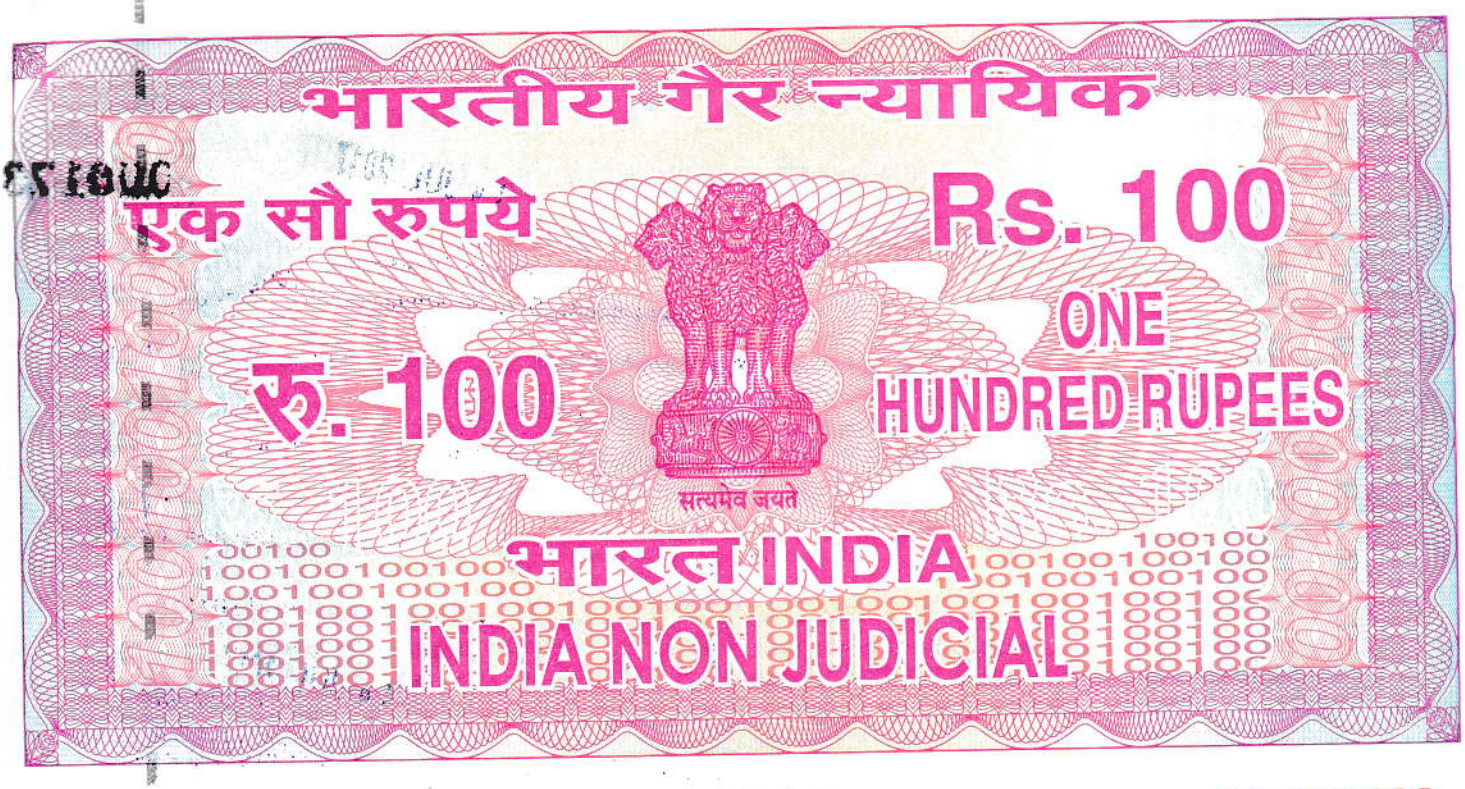

महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ SD 028225

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 event that the [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.

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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.

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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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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.