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
INDIA STAMP DUTY MAHARASHTRA Rs.0000100/-PB5145
Special Adhesive AUG 09 2016 14:0
61298 186563

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"