ગુજરાત GUJARAT

નંબર : 58016 રૂ.૧૦૦

BP 506421

તારીખ : ૨૯ માર્ચ ૨૦૧૮

નામ : Cliantha Research Limited
Opp. Pushparaj Towers,
Nr. Judges Bunglows,

ઠેકાણું : Bodakdev, Ahmedabad-380054
Ph.:+91-79-26853088-92
Fax:+91-79-26853093

કે. જી. ફતરીયા

લા. નં. એસ.બી. ૪૨૮, ૪૨૯/૧૯૯૯

એ-૪, સ્નેહા ફ્લેટ, મેમનગર, અમદાવાદ ના સહીંદી

સ્ટેમ્પરની સહી.....

PROTOCOL NO.: CRL031816

This Clinical Trial Agreement (the **"Agreement"**) is entered into on the 07 day of February, 2019 (the **"Effective Date"**) by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Opp. Pushparaj Towers, Nr. Judges Bungalows, Bodakdev, Ahmedabad – 380 054, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its assignees and successors-in-interest)

AND

Dr. Som Lakhani, whose principal place of business is at **Sumandeep Vidyapeeth & Dhiraj General Hospital, Vadodara, Gujarat, India** (hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his/ her successors and permitted assigns)

Attested CTC

29/11/2022

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

Confidential

AND

Sumandeep Vidyapeeth, At & Po. Piparia, Ta. Waghodia , Dist. Vadodara-391760 , Gujarat, India (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest).

CRO, Institution and Principal Investigator are referred to herein individually as a "Party" and collectively as "Parties".

WHEREAS, CRO has been contracted by **Cadila Healthcare Limited**, Zydus Tower, Satellite Cross Roads, Ahmedabad 380015 Gujarat, India (hereinafter referred to as the "Sponsor") to perform one or more of Sponsor study related duties and functions for the clinical trial entitled as "**A Randomized, Double-Blind, Multicenter, Three arm, Active and Placebo Controlled, Parallel Study to Evaluate the Bioequivalence (with clinical endpoint) of Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% (Cadila Healthcare Ltd, India) to EPIDUO® FORTE (Adapalene and Benzoyl Peroxide) Gel, 0.3%/2.5% (Galderma Laboratories, L.P., USA) in Subjects with Acne Vulgaris**" ("Study") according to Protocol Number "**CRL031816**", ("Protocol") including any subsequent duly authorized amendments and which is hereby incorporated by reference; and

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

WHEREAS, the Institution represents that it has the qualified personnel and facilities equipped according to Good Clinical Practices (GCP) to undertake the Study;

WHEREAS, Principal Investigator represents that he/she is appropriately qualified and experienced and has the authority and willingness to conduct the Study at the Institution;

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

1. THE STUDY AND THE PROTOCOL

A. The Study of **Adapalene and Benzoyl Peroxide Gel** (the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. **CRL031816** and entitled "**A Randomized, Double-Blind, Multicenter, Three arm, Active and Placebo Controlled, Parallel Study to Evaluate the Bioequivalence (with clinical endpoint) of Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% (Cadila Healthcare Ltd, India) to EPIDUO® FORTE (Adapalene and Benzoyl Peroxide) Gel, 0.3%/2.5% (Galderma Laboratories, L.P., USA) in Subjects with Acne Vulgaris**" (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of Sponsor by the CRO.

B. The Principal Investigator represents and warrants that he/she is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of his/ her curriculum vitae and other relevant documents as and when requested by the Sponsor, the Ethics Committee, CRO and the regulatory authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled

Lakhani

throughout the duration of the Study. The Principal Investigator should also ensure that he/she does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

C. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study.

D. **Conditions Precedent.** The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the reference-listed product with full prescribing information and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Institution under the supervision and direction of the Principal Investigator, who will conduct the Study according to the Protocol which may be amended from time to time in writing by the Sponsor.

E. Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an Ethics Committee / Institutional Review Board ("IRB") that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements.

F. **No Additional Research.** No additional research may be conducted on Subjects during the conduct of the Study by Institution and/or Principal Investigator unless it is approved and documented as a sub-study Protocol or an amendment to the original Protocol, after approval by the responsible Ethics Committee or IRB and DCGI or any other applicable regulatory authorities. Such prohibited research activities include, but are not limited to, analyses of biological samples from Subjects for any non-therapeutic purpose.

2. THE STUDY SCHEDULE

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

B. **Enrollment.** Principal Investigator shall be responsible for enrolling eligible subjects for the Study. Principal Investigator shall use the best efforts to recruit the Subjects and ensure unbiased selection of suitable Subject in accordance with the terms of Protocol. Principal Investigator will enroll minimum **40-45 Subjects** (as per the randomization schedule provided) and not more than **50 Subjects** (as per the randomization schedule provided) (the **"Site Maximum"**) for the duration of enrollment. The Principal

Lakhani

Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor either directly or through the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Sponsor has informed the Principal Investigator and/or Institution to stop the enrollment;

iv. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under applicable laws and requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed within the time period, as mutually agreed by & between the Parties hereto, **three (3) days** from each Subject's visit. If any tests are to be performed after the Subject's visit, CRF shall be completed maximum within **three (3) days** from receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Institution, CRF for such Subject must be completed within **three (3) days** from such Subject's last visit to the Institution. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed/emailed to Sponsor and CRO within **twenty four (24) hours** of i) such event's occurrence; or ii) such event's occurrence was noted; or iii) such event's occurrence was recognized, whichever event occurs earlier. Principal Investigator and Institution shall ensure that the Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

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

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

3. **PAYMENT**

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Payee (defined below) all direct and indirect costs incurred by the Payee in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated

herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque/electronic transfer to the Payee as per the details mentioned under Exhibit A, attached hereto. Payment shall be made within thirty (30) days after CRO has received invoice from the Payee.

For the purpose of this Agreement, "Payee" shall mean the person/ entity, details whereof, are more specifically mentioned under Exhibit A of this Agreement.

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

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

The foregoing notwithstanding:

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

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the Payee as per the details mentioned in Exhibit A of this Agreement.

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

F. **Payments for Screen Failure:** CRO, on behalf of the Sponsor, will pay **Rs.1000/-** (One Thousand Only) per Subject for screen failure. The maximum ratio for screen failure Subjects shall be **5:1** i.e. maximum **one** screen failure per **five** randomized Subjects. Subject discontinued/withdrawn after screening will be considered as screen failure and payment for screen failure will be provided as per above mentioned statement.

SUMANDEEP VIDYAPEETH

Lakhani

G. **Payment for Study Coordinator:** Payee will ensure that payments to Study coordinator / involved Study team are made in a timely manner to ensure that the quality and deliverables of the project are not affected at any phase of the Study.

H. All payments payable by CRO, on behalf of the Sponsor, are subject to deduction of taxes at source ('TDS') as per the applicable law unless relevant exemption certificate is produced by the Payee. GST will be paid, if applicable, on generation of valid invoice showing the amount of GST to be charged before any payment is made under this Agreement.

4. **OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR**

A. **Ethics Committee /IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the Ethics Committee / IRB of the Protocol and the Subject's informed consent form. The Principal Investigator shall provide the CRO and/ or the Sponsor or Sponsor's designee with written confirmation of the Ethics Committee / IRB's approval prior to the treatment of Subjects. If the Ethics Committee /IRB withdraws approval of the Study, at any time, the Principal Investigator shall immediately notify to the Sponsor and/ or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct & supervise the Study solely at the Institution. Principal Investigator and Institution will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the Ethics Committee /IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the CRO and/ or the Sponsor.

C. **Patient consent and entry into Study.** Along with complying with the requirements of the Declaration of Helsinki, the principles of Good Clinical Practice and other legislation appropriate to clinical trials, medical treatment, and the processing of personal and medical data, the Principal Investigator shall, before entering a Subject into the Study:

SUMANDEEP VIDYAPEETH

Lakhani

i. exercise independent medical judgement as to the compatibility of each prospective Subject with the requirements of the Protocol;

ii. advise the CRO of all instances in which, in the Principal Investigator's judgment, there is any question as to any prospective Subject's suitability for participation in the Study, and abide by the CRO's or Sponsor's decision as to whether or not to enrol that Patient;

iii. ensure that, before their participation in the Study, the Subjects are duly informed about all aspects of the Study that are relevant to them, including the purpose, duration, nature, significance, implications, and risks of the Study; and the processing, auditing, and monitoring of Subjects' data (including personal data) under this Agreement.

iv. ensure that, before his or her participation in the Study, each Subject has given his or her informed consent by signing a consent form in accordance with the Protocol;

v. acknowledge that the use of the consent form does not release the Principal Investigator from his/ her legal and contractual obligations relating to informed consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

vi. comply with the procedures described in the Protocol in relation to that Subject; and

vii. ensure that any data or supportive documentation provided to the Sponsor and CRO does not include any information that would personally identify a Subject.

D. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his/ her responsibilities under this Agreement, the Principal Investigator shall immediately notify the CRO and/or Sponsor or their designees and the CRO and/ or the Sponsor or their designees shall endeavor to agree upon a successor. In the absence of a prompt agreement upon a successor, the CRO may terminate this Agreement as set forth in clause 12(B) below.

E. **Sponsor Visits.** The Parties agree that the Sponsor and/or the CRO or their authorized representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the Ethics Committee /IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the informed consent form and appropriately authorized by the Subject and the Ethics Committee /IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor and/or CRO or their authorized representative.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and/or CRO or their authorized representative and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory

agencies during or after the completion of the Study. The Institution and the Principal Investigator shall notify the Sponsor and/or CRO or their authorized representative by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, a written notice of the intended or possible inspection shall be sent to the Sponsor and/or CRO or their authorized representative within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit authorized representatives of the Sponsor and/ or CRO to review and comment on such response prior to it being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor and/or CRO or their authorized representative with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. **Supplies.**

a. The Parties agree that the Sponsor or Sponsor's designee shall supply to the Institution, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the ancillary drugs, materials, equipment and information which the Protocol specifies. The Institution and the Principal Investigator acknowledge that the Study Drug as well as the ancillary drugs are experimental in nature, and therefore shall use prudence and reasonable care in its use, handling, storage, transportation, disposition and containment. The Institution and the Principal Investigator acknowledge that the Study Drug as well as the ancillary drugs shall be used only as specified in the Protocol. Any other use of such drugs constitutes a material breach of this Agreement. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs as well as ancillary drugs, devices/ equipments and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs, be destroyed in accordance with instructions provided by the Sponsor through CRO. The Parties agree that the Sponsor shall solely own all rights, title and interest in the Study Drug, including ancillary drugs and any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug as well as of ancillary drugs hereunder, and/or the possession or use of the Study Drug as well as of ancillary drugs by the Institution or Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or the ancillary drugs or other transfer of title in or to the Study Drug or the ancillary drugs. Further, the Institution and the Principal Investigator shall use the Study Drug as well as the ancillary drugs solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor directly or through the CRO.

b. The instruments, materials or other equipments, if any, supplied/provided by the CRO to the Institution shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under this Agreement and shall be stored under conditions that are appropriate to the nature of the equipment and that minimize the risk of loss or damage.Any damage caused to

such instruments, materials or other equipments supplied/provided by the CRO under this Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Institution and no liability of the same shall be placed upon the CRO.

G. Study Records, Reports, and Data.

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

All the source documents pertaining to clinical conduct of the Study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

ii. *Case Report Forms.* The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the Ethics Committee / IRB annually, or more frequently, if requested by the Ethics Committee /IRB.

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

v. The Parties agree that in case the Principal Investigator is no longer associated with the conduct of the Study, the Institution, Institution's head or authorized

designee will be responsible for maintenance and retention of Study Records until a successor investigator is appointed as per clause 4(D) of this Agreement.

vi. **Analysis samples.** The Sponsor or its designees will test biological samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor through the CRO will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator.

H. Reporting of Serious Adverse Event (SAE). The Institution and Principal Investigator shall notify CRO and Sponsor of any SAE encountered in the Study within **twenty four (24) hours** in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax/email, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements. Institution and Principal Investigator shall indemnify and hold harmless the CRO and Sponsor for any failure to observe or compliance of any laws. Institution and Principal Investigator shall bear all the resultant whatsoever liability (ies) arising thereof due to such failure.

I. Institution and Principal Investigator undertake to provide full and immediate access to, as well as to maintain, information and witnesses surrounding the occurrence of any Subject injury as is sufficient for CRO and/or Sponsor to conduct an investigation concerning such injury.

In the event that:

i) the Subject injury is caused due to failure in following the Protocol or by negligent and willful actions or omissions of Institution, its officers, directors, employees, or agents or Principal Investigator; and/or

(ii) Institution and/or Principal Investigator fails to promptly notify CRO and/ or Sponsor of a Subject injury as required herein;

CRO shall treat such failure of Institution and/or Principal Investigator as amounting to material breach of this Agreement.

J. Resolution of Discrepancies. Principal Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the Subject's medical records.

5. CONFIDENTIALITY

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

(as defined below) for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

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

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

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

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

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

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

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of stopping or preventing any existing or anticipated breach of the terms of Confidentiality and of any other terms of this Agreement.

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

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, the Receiving Party shall not disclose to any third party any Confidential Information and shall not use for any purpose other than as expressly provided for herein, any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are

bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the Disclosing Party to obtain a protective order or to prevent disclosure.

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

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

F. **Individually Identifiable Health Information.** If, in connection with the Study or performance of this Agreement, either Party comes into contact with individually identifiable health information relating to subjects who are not Study Subjects, such Party agrees to maintain the confidentiality of such information and not to use it for any purpose.

6. PUBLICATION

The Parties agree that subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

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

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

B. **Patents and Inventions.**

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

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

iii. The Parties agree that the New Inventions or Discoveries made jointly by the Institution, Principal Investigator or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor. Institution and Principal Investigator shall assign and transfer to Sponsor without further consideration, the entire right, title and interest globally in all Sponsor intellectual property of any New Inventions or Discoveries made or any process carried out in the name of Sponsor. Institution and Principal Investigator acknowledge that all original works of authorship made whether by Institution and Principal Investigator under this Agreement are "works made for hire" and agrees to assist Sponsor in obtaining patent or other intellectual property protection thereof.

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

v. Institution and / or the Principal Investigator shall promptly notify the Sponsor with a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. CRO shall communicate to the

Dr. Som Lakhani

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

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

8. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. **Of the Principal Investigator.** The Principal Investigator, in addition to his/her representations under clause 1(B) above, represents and warrants that (i) he/she has the legal authority and right to enter into this Agreement; (ii) he/she has no obligation to any third party that is in conflict with or has the potential to conflict with, its obligations under this Agreement; (iii) he/she has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he/she will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by him/ her and constitutes a valid, binding obligation enforceable against him/ her in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he/she was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he/she has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the CRO or the Sponsor, and attached to this Agreement as an Exhibit

hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of inspectional observations (FDA Form 483), notices of adverse findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation **("Notice of Intent to Disqualify**"). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events mentioned in this paragraph occur during the course of this Study, the Principal Investigator shall provide the CRO and/ or Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the CRO shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his/her own behalf that he/she has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the CRO and/ or Sponsor immediately and the CRO shall have the right to terminate this Agreement immediately without further cost or liability.

B. **Of the Institution.** Institution, in addition to its representations under clause 1(C) above, will ensure that the Principal Investigator remits to the Sponsor and/ or CRO, all clinical data, including without limitation, CRFs, medical reports and the information generated during the performance of the Study. Institution will notify the CRO and Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

C. **Of the CRO.** The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the its obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

CRO, on behalf of the Sponsor, represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory

control of the DCGI or FDA and/or comparable foreign agencies in connection with any Study Drug or device administered or used pursuant to the Protocol. In particular, CRO shall ensure that the Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

D. **No Other Representations or Warranties.** Except for the limited representations and warranties given in this clause 8, none of the Parties hereto makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

9. GOVERNING LAW

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

10. INDEMNIFICATION

A. **Sponsor Indemnification.** CRO agrees that the Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnitees**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnitees or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in clause 11 below and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnitee, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and CRO and their respective directors, officers, employees, agents, successors, and assigns ("**Sponsor Indemnitees**") from and against any and all

third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnitees or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor/CRO concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnitee, or any other person on the Institution's property or under its control, exclusive of the Sponsor/CRO's employees and (iii) a breach of any terms of the Agreement and the representations and warranties made by Principal Investigator or Institution jointly and / or severally.

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

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

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

F. **Subject Injury.** CRO agrees that the Subjects shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of Subject injury or death during the conduct of Study in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

11. INSURANCE

A. **Sponsor Insurance.** CRO agrees that the Sponsor shall maintain during the term of this Agreement and for a period of **One (1) year** thereafter, general liability insurance (with product liability endorsements) sufficient to meet its indemnification obligations under this Agreement. CRO shall provide evidence of insurance upon request and will provide to the Institution, **thirty (30) days** prior written notice of cancellation of its coverage.

SUMANDEEP VIDYAPEETH

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet their indemnification obligations on appropriate conditions and shall provide evidence of the insurance upon request by the Sponsor and/ or CRO and shall also provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This clause 11 shall survive termination of this Agreement.

12. TERM AND TERMINATION

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to clause 4(G)(*iv*), above, unless earlier terminated in accordance with this Agreement.

B. **Termination.**

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

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

b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

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

ii. This Agreement may be terminated by either Party, upon thirty (30) days prior written notice, if the other Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with an opportunity to cure the default/ breach, from the other Party.

iii. This Agreement may be terminated by the CRO immediately, if the Principal Investigator is unwilling or unable (for whatsoever reason) to continue to act as a Principal Investigator and a successor, acceptable to both Institution and CRO and/ or Sponsor has not been found within 30 days therefrom, in accordance with clause 4(D) of this Agreement.

iv. If Principal Investigator fails to enroll minimum number of Subjects as mentioned in clause 2B above, the CRO shall be free to prematurely terminate the participation of Principal Investigator in the Study.

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

SUMANDEEP VIDYAPEETH

Lakhani

vi. Upon the effective date of termination, there shall be an accounting conducted by the Institution, subject to verification by CRO and/ or Sponsor. Within thirty (30) days after receipt of adequate documentation there from, CRO shall make payment to Institution for.

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

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

vii. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by CRO and/ or Sponsor, to the extent medically permissible.

vii. **Immediate Termination by the Sponsor.** The Parties agree that the Sponsor may direct CRO to terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator and/ or Institution; a) if the Sponsor, in its sole discretion, deems necessary that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in clause 2 prior to the shipment of the Study Drug to the Institution.

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

ix. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the

Agreement, together with the provisions of Clauses 4, 5, 6, 7, 9, 10, 12 and 13 shall survive any termination of this Agreement for any reason.

13. MISCELLANEOUS

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

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

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

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

Any notice to the **Sponsor** shall be addressed as follows:

Address: Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads,
Ahmedabad 380015 Gujarat, India
Tel# +91-79-2686 8100; Fax# +91-79-2686 2368

Any notice to **Institution** shall be addressed as follows:

Address: Sumandeep Vidyapeeth , At & Po. Piparia , Ta.Waghodia , Dist. Vadodara-391760 , Gujarat, India

Attn: Dr. Manoj M Sattigeri
Mobile No. : +91 98244 66105
Phone: 02668 245264

SUMANDEEP VIDYAPEETH

Lakhani

Any notice to **Principal Investigator** shall be addressed as follows:

Address: Sumandeep Vidyapeeth & Dhiraj General Hospital, At & Po. Piparia, Ta.Waghodia , Dist. Vadodara-391760 , Gujarat, India

Attn: Dr. Som Lakhani

+91- 9825350198

Any notice to **CRO** shall be addressed as follows:

Cliantha Research Ltd.,
Garden View Corporate, House No.8,
Off Sindhu Bhavan Road,
Opposite Auda Garden, Bodakdev,
Ahmedabad – 380 054

Attention: Dr. Dharmesh Domadia,
Associate Vice President - Global Clinical Operations
+91-79-66219 555 (phone); +91-79-66219 549 (fax)

E. **Assignment** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

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

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

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

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

SUMANDEEP VIDYAPEETH

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

K. **Covenant Not to Hire**. CRO agrees that the Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this section) until one year following termination or expiration of this Agreement, unless Institution gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

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

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

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

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

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

SUMANDEEP VIDYAPEETH

Lakhani

Duly authorized representatives of the Parties have entered into this Agreement on the dates written below.

INSTITUTION

By: _____

(Signature & Date)

Dr. Manoj M Sattigeri
The Registrar

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

PRINCIPAL INVESTIGATOR

By: Lakhani 19/02/2019

(Signature & Date)

Dr. Som Lakhani
Principal Investigator

CRO

CLIANTHA RESEARCH LIMITED

By: _____

(Signature & Date)

Dr. Dharmesh Domadia
Associate Vice President - Global Clinical Operations

EXHIBIT A: PAYEE DETAILS

The further details for the payments should be provided as:

Name of Payee	Research Cell Sumandeep Vidyapeeth
Name of Bank	Indian Overseas Bank
Account No.	178802000000131
IFSC Code	IOBA0001788
S.W.I.F.T. Code	IOBAINBB105
PAN No.	AAATK4485H
GST Number	GST No.: 24AAATK4485H1ZK HSN No.: _____ **or** SAC No.:998113
Payee Address	Sumandeep Vidyapeeth, At & Po Piparia, Ta. Waghodia, Vadodara 391760
Branch Address	Piparia Branch, K M Shah Dental College Campus, Waghodia Road, Piparia 391760, Dist Vadodara
Contact Details of payee	02668 245264

Lakhani

Exhibit B: Budget and Payment Schedule

BUDGET:

Principal Investigator : Dr. Som Lakhani

Site Address : Sumandeep Vidyapeeth & Dhiraj General Hospital, At & Po. Piparia, Ta. Waghodia, Dist. Vadodara - 391760, Gujarat, India

CRL031816: Per Patient Grant							
Investigator Grant (All amounts in INR)							
Patient Visits	Screening, Visit-1	Baseline, Visit-2	Week 4, Visit 3	Week 8, Visit 4	Week 12, Visit 5	Safety FU, Telephonic Visit 6	**Total**
PI Charges	3500	2500	2500	2000	3500	500	**14500**
Lesion Photographs Charges	0	500	500	0	500	0	**1500**
Study Coordinator Fees	1500	1500	1500	1000	1500	500	**7500**
Patient travel compensation	500	500	500	500	500	0	**2500**
Institutional Overhead, 20% of PI & Study Coordinator Fees	1000	800	800	600	1000	200	**4400**
Total charges per visit	6500	5800	5800	4100	7000	1200	**30400**
Grand Total							**30400**

Budget notes, payment schedule, conditions of payment and payment directions
Note 1: Patient travel reimbursement with maximum cap of INR 500 per visit based on actual patient travel invoices/bill.
Note 2: AE/SAE compensation and/or medical management as per Regulatory Requirement (During SAE management consultant charges if any, will be provided only for consultant who is not a part of study team. Consultant who is part of study team will not be reimbursed for extra visit/charges)
Note 3: Screen failure payment will be done on 5:1 basis i.e. maximum one screen failure per Five randomized patient
Note 4: PI Charges includes Serum Pregnancy Test to be performed on Visit 1 and 5 at Local Lab.
Note 5: Grand total is inclusive of Archival charges or any other charges

PAYMENT SCHEDULE FOR THE ADVANCE PAYMENT IS AS FOLLOWS:

A. **Study start up cost (Advance/ pre payment) INR. 25000/- (Twenty Five Thousand Rupees Only)**

The advance payment (pre payment) provided to the Payee will be adjusted against first invoice raised by the Payee as per the Per Subject Grant mentioned above.

The remaining payments will be provided on monthly basis as per the Subject visit charges/ Subject Study completion.

Sponsor will pay only **INR 1000/-** for screen failure Subjects as mentioned in clause 3F of this Agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per five randomized Subjects. Any Study Subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from Study without any payments. CRO reserves the right to withhold payment for any Study Subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

B. Payment Adjustments

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

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

In the event this Exhibit sets forth a maximum number of Subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize an increase in Study Subjects and/or payment amounts.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

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

C. Invoices

Send invoices to: Cliantha Research Limited

Contact Person: **Mr. Hitesh Maheshwari**

Address: Cliantha Research Ltd. - Ahmedabad,
Garden View Corporate House No. 08, Opposite AUDA Garden, Bodakdev, Ahmedabad - 380054, Gujarat

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

D. Final Payment

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

SUMANDEEP VIDYAPEETH

Lakhani

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

1. All amounts above are in Indian Rupee (INR).
2. Lab Investigations: The Study requires lab examination at screening, and end of Study for Female participant. The local lab investigation charges if any will be reimbursed on actual.
3. Serious Adverse Event related costs: Costs relating to SAE that arise due to Study participation would be borne by the Sponsor on actual.
4. Please note that approx. 10 % of the total amount for one randomized Subject only i.e. **INR. 3040/-** (Three Thousand Forty Rupees Only) will be considered as retention amount and will be paid at the end of Study/ Study close out; once all the Study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.
6. A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the Payee in the budget.
7. GST (as applicable) will be considered on total grant amount subject to availability of GST number with the Payee. GST will be paid and applicable to the Payee, provided they reflect the GST number on Invoices / Bills generated by them.
8. In case recruitment is not initiated within a reasonable time period notified by CRO in writing, unutilized amount (as mentioned in the payment head above) shall be be returned to Sponsor.

Attested CTC

29/11/2022.

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

Lakhani