INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

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Certificate No.	:	**IN-GJ57372553186457S**
Certificate Issued Date	:	21-Oct-2020 06:14 PM
Account Reference	:	IMPACC (AC)/ gj13207711/ GULBAI TEKRA/ GJ-AH
Unique Doc. Reference	:	SUBIN-GJGJ132077115243463454569 5S
Purchased by	:	CADILA PHARMACEUTICALS LTD
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CADILA PHARMACEUTICALS LTD
Second Party	:	NA
Stamp Duty Paid By	:	CADILA PHARMACEUTICALS LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

This E-Stamp Certificate forms an integral part of the Clinical Trial Investigator's Agreement dated 23rd October 2020 is by and between

1) Cadila Pharmaceuticals Ltd.
2) Dr. Kishan Nimma
3) Sumandeep Vidyapeeth
4) RAV Research Private Limited.

Attested True

ACC SHAH

LB 0011707451

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

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CLINICAL TRIAL INVESTIGATOR'S AGREEMENT

This **CLINICAL TRIAL INVESTIGATOR'S AGREEMENT ("Agreement")** is made effective as on this 23rd October, 2020 ("the Effective Date");

CADILA PHARMACEUTICALS LTD., a Company incorporated under the Companies Act 1956, having its registered office at "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Dist. Ahmedabad and it's Contract Research Operations Division (hereinafter referred to as "Sponsor" or "Sponsor") situated at, 1389, Trasad Road, Dholka-382225, Dist: Ahmedabad, Gujarat, India.

And

DR KISHAN NINAMA, as the Investigator at the Institution, working as a medical practitioner at Department of Skin & VD, Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta. Waghodia, Vadodara 391760 (hereinafter the "Investigator") of the SECOND PART;

And

SUMANDEEP VIDYAPEETH an Institution Deemed to be University, At & Po Piparia, Ta. Waghodia, Vadodara 391760, represented by **Dr Chandramani B More, Registrar** (hereinafter the "Institution"), which term unless repugnant to the context and meaning thereof be deemed to include its affiliates, successors, assigns and legal representatives of the THIRD PART;

And

RAV RESEARCH PRIVATE LIMITED, having its registered office at, 2A/2,Shree Gokul CHS, Vrindaban Society, Thane (west) 400601, Maharashtra India represented by **Dr. Romita Gujar**, Director (hereinafter referred to as the "SMO", which expression, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and permitted assigns) of the FOURTH PART;

'Cadila CRO, 'Institution', 'Investigator' and SMO, hereinafter are collectively referred to as the "Parties" and individually as the "Party".

Recitals

(A) WHEREAS, Cadila Pharmaceuticals Limited is a renowned pharmaceutical company of India and engaged in the development, manufacturing and marketing of pharmaceutical and allied products.

(B) WHEREAS Cadila CRO, intends to conduct a multi-center clinical study of A MULTI-CENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL-GROUP STUDY, COMPARING ADAPALENE AND BENZOYL PEROXIDE GEL, 0.3%/2.5% (CADILA PHARMACEUTICALS LIMITED) TO EPIDUO® FORTE (ADAPALENE AND BENZOYL PEROXIDE) GEL, 0.3%/2.5%, GALDERMA

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LABORATORIES, L.P.) AND BOTH ACTIVE TREATMENTS TO A PLACEBO CONTROL IN THE TREATMENT OF ACNE VULGARIS (hereinafter referred to as "Clinical Study").

(C) WHEREAS the Investigator has represented that, he is a qualified medical practitioner, working with the Institution and competent to render the services as an Investigator for the Clinical Study which is a subject matter of this Agreement and also giving his consent to the render his services to Cadila CRO and/or Institution.

(D) WHEREAS, the Institution has represented that it has appropriate facilities, personnel, other resources, and the Investigator (as defined above) having the requisite qualification, training, knowledge and experience necessary to conduct the above said clinical study and laboratory test evaluations.

(E) WHEREAS, SMO has represented to Cadila CRO that it is equipped with the requisite knowledge, skill, expertise, facilities and resources, required to render services to the CRO, Institution and Investigator pertaining to the Clinical Study. The SMO shall facilitate, assist, support and coordinate with the Institution and Investigator to conduct the above said Clinical Study in accordance with this Agreement, Protocol Number. For purposes of this Agreement, the term "SMO" shall include all employees, executives, officers, directors, faculty, staff and other authorized agents of the SMO.

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

1. Scope of Work.

The Investigator agrees to conduct the Clinical Study subject to the terms of this Agreement, Protocol Number (**ADBG1910**) (the "Protocol"), which shall be deemed to have been incorporated by reference to this clause and the investigator's brochure for the investigational Product (the "Investigator's Brochure") provided by the Cadila CRO, under Investigational New Drug (IND) applications filed with the Drugs Controller General of India (DCGI). The Investigator agrees to conduct the Clinical Study strictly in accordance with the Protocol approved by the local Ethics Committee, as amended from time to time. Investigator will conduct the Study in strict accordance with the terms and conditions of this Agreement, the Protocol and any amendments thereto, and in compliance with all federal, state and local laws and regulations as applicable to the territory in which the Study is being conducted including but not limited to (a) The revised and applicable versions of the Declaration of Helsinki Directive, as amended from time to time; (b) New Drug Clinical Trial Regulations, 2019 , as amended from time to time; (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("ICH/GCP"); (c) all regulations and laws as applicable to clinical trials in India (d) the Prevention of Corruption Act, 1988. The Clinical Trial Annual report to be submitted to Ethics Committee every year.

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1.1 Obligations of SMO:

(i) SMO shall support Sponsor/CRO in finalizing Institution and the Investigator;

(ii) SMO shall ensure to support investigator to finish the enrollment of subjects; and all study related documents and timely support for updation of Site Master File, Study related communication with Sponsor, Investigator, Ethics Committee (EC) & patients.

(iii) SMO shall recieve, store, dispense supplies from Sponsor including Investigational Products, patient diaries, files and other data collection tools etc. and shall complete Case Report forms (CRF) as per the protocol requirement.

(iv) SMO shall facilitate, monitoring/ inspection of the Study by Sponsor/ EC/ Regulatory body. SMO shall support Investigator for archival of all Study related documents as per regulatory requirements.

(v) SMO shall ensure that all Adverse Events at site (i.e. death, life threatening, or serious adverse event as specified in the Protocol) shall be reported to Institutional Ethics Committee with a copy to SPONSOR. Such notification shall be given promptly, and in no instance later than 24 (twenty-four) hours of occurrence of such an event and shall be made in accordance with NDCT Rules 2019 and the procedures outlined in the Protocol concerning the reporting of adverse events.

2. The Investigator.

2.1 For sake of clarity, the Investigator is a medical practitioner working with the Institution and will be named in Annexure I. The Investigator represents and certifies to have read and understand the Investigator's Brochure. Prior to the commencement of the Clinical Study, the Investigator shall deliver to Cadila CRO true, complete and correct copies of the Investigator's statement as mentioned in New Drug Clinical Trial Regulations, 2019, as amended from time to time and curriculum vitae, each of which shall be signed by the Investigator. During the Clinical Study, the Institution shall immediately notify Cadila CRO in writing when it becomes aware that the Investigator plans to leave the Institution or shall be unable to complete the Clinical Study. If the Institution and Cadila CRO are unable to agree on an acceptable substitute investigator within fifteen (15) business days following such notice, Cadila CRO may terminate this Agreement pursuant to Section 16.

3. Representations and Covenants.

3.1 The Institution and (to the extent that such representations and covenants relate to the Investigator) the Investigator each represents certifies and covenants to Cadila CRO, as follows:

(a) The Investigator is, and at all times during the course of the Study shall be, qualified by training and experience with appropriate expertise to conduct the Study;

(b) The Institution and the Investigator have, and at all times during the course of the Clinical Study shall have, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Clinical Study;

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(c) None of the Institution, the Investigator, or any other person who assists in performing the Clinical Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Clinical Study or has entered into any contract with respect to the Clinical Study that might interfere with the performance of the Clinical Study or that might impair the acceptance of the resulting data by the regulatory authority or that might create a conflict of interest;

(d) The Institution and the Investigator have been selected to conduct the Clinical Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any Cadila CRO's Product.

4. Facilities.

4.1 The Institution and the Investigator shall conduct the Clinical Study at the facilities situated as mentioned first herein and identified above, or such other facilities as Cadila CRO and the Institution may agree in writing, The Institution shall make available it's personnel, facilities and resources as may be necessary to perform its obligations efficiently and expeditiously under this Agreement.

5. Subject Enrollments and Informed Consent

5.1 Subject Enrollment: The Investigator shall enroll such nos. of subjects into the Clinical Study as mentioned in Annexure I annexed herewith and forming integral part of this Agreement (each, a **"Subject"**). The Investigator shall use all reasonable efforts to complete enrollment of all Subjects by Enrollment Closing Date set forth in Annexure I or otherwise by such other date as may be notified in writing to the Investigator by Cadila CRO. The Study period may be extended or shortened and the number of Subjects the Institution/Investigator may enroll in the Clinical Study may be changed at Cadila CRO's sole discretion. The Institution/Investigator acknowledges that the Clinical Study is part of the Multi-Center Study, and agrees that when the enrollment goal for the Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

5.2 Informed Consent: The Investigator shall obtain the informed consent form of each Subject prior to any screening or participation in the Clinical Study using the Informed Consent Materials (as defined in Section 7.6) and in compliance with Applicable Laws. Each Subject shall complete an informed consent form that has been reviewed and approved in advance by IEC of the Institution in compliance with the requirements of applicable laws. Investigator has to ensure that the Informed Consent is only voluntary and the study participant has the rights to withdraw from the trial at any time during the Clinical Study.

5.3 Investigator shall report any death, life threatening, or serious adverse event, or other event as specified by the Protocol to the Institutional Ethics Committee with a copy to Cadila CRO. Such notification shall be given promptly, and in no instance later than 24 (twenty-four) hours of occurrence of such an event and shall be made in accordance with New Drug Clinical Trial Regulations, 2019, as amended from time to time and the procedures outlined in the Protocol concerning the reporting of adverse events.

5.4 Compensation. In consideration of the services to be rendered hereunder by the Institution and Investigator, Cadila CRO shall pay to the SMO, such amounts in a manner stipulated in the payment schedule set forth in Annexure –1 annexed herewith and forming an integral part of this Agreement. The parties acknowledge that the amounts to be paid by Cadila CRO under this Agreement are reasonable

compensation for the work performed and that neither the Institution nor the Investigator has received any other compensation or other inducement in connection with this Agreement for its participation in the Clinical Study. Any amounts, if any, paid by Cadila CRO to the Institution for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly refunded to Cadila CRO upon the completion of the Clinical Study or expiration or termination of this Agreement, or earlier at the written request of Cadila CRO except with respect to those expenses reimbursable under Sections 14.2. The Institution acknowledges and agrees that the payments made by the Cadila CRO under this Section represent Cadila CRO's total monetary obligations under this Agreement, and fully cover the costs of conducting the Clinical Study. Accordingly, the Institution shall not submit claims to, or otherwise seek reimbursement from any other third party paid or, whether public or private, for any costs covered by payments made or goods or services provided by Cadila CRO under this Agreement or otherwise incurred for conducting the Clinical Study. Cadila CRO shall ensure compensation for the SAE period over and above covering / reimbursement of the research injury due to SAE as per protocol specifications read with New Drug Clinical Trial Regulations, 2019, as amended from time to time.

5.5 In the event INVESTIGATOR screens and/or enrolls very few patients, through no fault of the Cadila CRO, Cadila CRO may close enrollment at the Institution without liability thereof. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Subjects, the Institution shall immediately inform the Cadila CRO in writing. In each such event, the Parties shall discuss the consequences of the delay and if reasonable, as determined by Cadila CRO, each Party shall undertake reasonable endeavors to agree on measures to overcome such a delay.

6. Ownership and Control of Study Drug.

6.1 All Study Drug supplied to the Institution shall remain the exclusive property of Sponsor until administered or dispensed to Subjects during the course of the Clinical Study. The Study Drug shall only be used for the purpose and manner as described in the Protocol and in compliance with Applicable Laws. Upon termination or completion of the Clinical Study, the Institution shall, at Sponsor's direction and expense, either return to Sponsor or Cadila CRO or dispose of any quantities of unused Clinical Study Drug, in accordance with Cadila CRO's written instructions. The Institution shall maintain complete and accurate records relating to the disposition of the Study Drug supplied to the Institution as set forth in Section 7.1.

6.2 Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, CT scans, MRI scans, PET scans, ultrasounds, subject files, and records kept at the pharmacy, at the laboratories involved in the Clinical Study in accordance with Applicable Law (collectively, "Source Documents") however, Institution shall bound to provide the source documents to Cadila CRO as and when demanded by it for the purpose of evaluation and records of the study and its outcome, or any other reason.

7. Records; Reports; and Regulatory Assistance.

7.1 Study Documentation: The Institution and the Investigator shall be jointly liable to prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation in a manner acceptable for the collection of data for submission to, or review by regulatory or governmental authorities, and in full compliance with the Protocol and all Applicable Laws. However, on a case-by-case basis, Cadila

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CRO may at its sole expense request, in writing, longer periods of retention times for Study Documentation. For purposes of this Agreement, "Study Documentation" includes all records (related to the Study Drug or Protocol), accounts, notes, reports and data, collected, generated or used in connection with the Study, whether in written, electronic, video or other tangible form, including all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Clinical Study. The Investigator or designee will conduct data entry activities, which shall include entry of Subject data after Subject visit within 3 working days after a visit and Investigator shall respond to all data queries within 7 (seven) days from the date of such request. The CRF instructions will also provide the Study site with data entry instructions. A duplicate copy of the CRF will be archived at the Study site for 15 years after the study completion.

7.2 The Cadila CRO will review the facilities at the Site to ensure adequate infrastructure required for Clinical Study at the site. INVESTIGATOR shall ensure that the Institution shall maintain at all time an adequate facilities for the duration of the Study (i.e. at a minimum, are safe, secure, hygienic, include adequately-maintained and calibrated equipment, and provide for secure and accessible storage of Study materials and records). Study Records will be retained by Investigator for 2 (two) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until 3 (three) years after the study is complete and FDA / DCGI is notified, or any longer retention period mandated by Applicable Law.

7.3 The Investigator agrees to limit access to the Investigational Product to only qualified and delegated Clinical Study staff and shall personally ensure, administer, instruct administration, or supervise the administration or instruction of administration of Investigational Product (whether active or placebo) to Clinical Study patients in accordance with the Protocol; and shall not chemically, physically or otherwise modify Investigational Product; and shall handle, store, and ship or dispose of Investigational Product with due and appropriate care and in compliance with manufacturer's instructions and all Applicable Laws, rules and regulations, including, but not limited to, those governing hazardous substances.

7.4 The Investigator agrees to limit access to the Biological sample, specific marker sample, surrogate marker sample and or sample / test as per protocol to only qualified and delegated staff and shall personally ensure sample collection, processing, storage, transport, handling and or concerned activities in accordance with protocol and timeline.

7.5 Provisions of Data and Reports: The Institution shall provide to Cadila CRO original case report forms for each Subject participating in the Clinical Study and such other reports as and when required by the Protocol or under Applicable Laws.

7.6 Institutional Review Board: The Institution shall provide to the Cadila CRO documentation verifying review and approval by the IRB of the information to be provided to potential Subjects of the Clinical Study to secure their informed consent, including information about any compensation being provided to Subjects for participation in the Clinical Study ("Informed Consent Materials"), the Protocol, the Investigator's Brochure and amendments to any of the foregoing.

7.7 Regulatory Assistance: At the request and expense of Cadila CRO, the Investigator or his representative shall: (a) assist Cadila CRO in the preparation and submission of investigational new drug applications, new drug applications, any other premarket or marketing applications relating to the Clinical Study or the Investigational Drug, and any amendments or supplements; (b) attend meetings with regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such

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other reasonable assistance as the Cadila CRO may request in connection with regulatory matters relating to the Study or the Study Drug.

7.8 Sponsor shall timely arrange the Investigational Product to Cadila CRO who shall deliver the same at SITE of the Institution, in sufficient quantities for use in the Study. Title to these materials delivered by Cadila CRO shall remain solely and exclusively with Sponsor, and the materials shall be used solely and exclusively by Investigator for purposes of carrying out the Study.

8. Audit and Review:

8.1 Sponsor or its authorized representatives shall have the right, upon advance written notice, at Sponsor's expense, and during regular business hours, to: (a) audit all Facilities of the Institute being used in performance of the Clinical Study; (b) monitor the conduct of the Study and ensure to send monitoring follow up report promptly; (c) review, copy and audit all Study Documentation, any other books, records, data and Work Product (as defined below) relating to the Study or the IRB, and all required licenses, certificates and accreditation; and (d) interview the Investigator and other persons who assisted in performing the Study. Subject's medical records are for review purposes only. (e) Sponsor to send the DSMB report (if applicable) and its timely submission to EC. (f) Sponsor to notify to the Institution, up to two years post study closure, relevant safety findings from the study data.

9. Changes to the Protocol.

9.1 No change in the Protocol shall be made by the Institution or the Investigator, subject to any Applicable Laws relating to the safety of Subjects that require a deviation from the Protocol, in which case the Institution shall promptly notify Cadila CRO and the Institution Review Board of the nature of the deviation and the facts necessitating such deviation as soon as the facts are known to the Institution. Cadila CRO may at any time make changes in the Protocol upon five (5) days' advance written notice to the Institution; provided, however, that, unless the changes are required by Applicable Laws, do not materially increase the cost of performance of the Clinical Study by the Institution or are otherwise agreed to by the Institution, otherwise the Institution may mutually discuss with Cadila CRO on the material increase of the cost for performing Clinical Study due to change in Protocol.

10. Regulatory Inspections.

If any governmental or regulatory authority (a) contacts the Institution or the Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any Facility or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Institution, the IRB or the Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Institution shall promptly notify Cadila CRO of such contact or notice. Cadila CRO shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Clinical Study. The Institution shall provide Cadila CRO with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. Cadila CRO shall have the right in advance to review and comment on any responses that pertain to the Study. No such response shall contain any false or misleading information with respect to the Clinical Study, the Study Drug or Cadila CROConfidential Information

11. Confidential Information

11.1 For purposes of this Agreement, "Confidential Information" means any information of Cadila CRO, whether of a technical, business or other nature, including information that relates to Cadila CRO's trade secrets, products, Study Drug, chemical structure, promotional material, developments, proprietary

rights or business affairs, together with any Inventions, Work Product and all other written information, data and results collected, prepared, developed or generated by the Institution, the Investigator and any other person pursuant to or in contemplation of this Agreement, including, subject to applicable laws and regulations, this Agreement. Confidential Information does not include any information, if, the Institute and Investigator can demonstrate that the information:

(a) Is already in their possession and known prior to the date of this Agreement;

(b) The Institution or the Investigator can prove that they have lawfully obtained from a third party without breach of any obligation of confidentiality;

(c) is or becomes part of the public domain through no act or violation of any obligation of the Institution or the Investigator; or (For the avoidance of doubt, when Cadila CRO lists or discloses any non-confidential information relating to the Study Drug or the Study in a clinical trial registry or clinical results database, any aspects or details of Confidential Information concerning the Study Drug or the Study that are not listed or disclosed in such registry or database shall not be deemed to be or become part of the public domain.)

11.2 The Institution and the Investigator shall not, without Cadila CRO's prior written consent or as may be permitted by this Agreement, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. The Institution shall restrict the access of Confidential Information to only those persons within the Institution who have a need to know, and shall ensure that they are aware of the obligation of confidentiality required by this Agreement. The Institution and the Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its most sensitive confidential information. The Institution or the Investigator, as applicable, shall notify Cadila CRO promptly upon the Institution or the Investigator's discovery of any loss or compromise of the Confidential Information. Upon the termination or expiration of this Agreement or upon Cadila CRO earlier written request, the Institution or the Investigator shall promptly return to Cadila CRO all Confidential Information at Cadila CRO reasonable expense, provided that the Institution shall have the right to retain, copies of each Subject's primary medical records for archival purpose only.

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12. Publication and Presentations

12.1 Neither the Institution, the Investigator, nor any other person who assists in performing the Study shall issue any press release or other publicity materials or make any presentation or announcement, private or public, which refers the name of Sponsor/Cadila CRO or the name of Test Product, without prior written consent of Sponsor. There shall be no publication based on Trial unless Sponsor shall have given its prior written approval. Sponsor may require that Institution publish results jointly with them and others.

13. Use of name:

13.1 Subject to Applicable Laws, none of the Institution, the Investigator or Cadila CRO shall mention or otherwise use the name, trademark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such other Party except for the purpose as expressed herein this Agreement; provided, however, that for non-commercial, internal purposes, Cadila CRO shall have the right to identify the Institution as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The Institution may use the name of Cadila CRO and the title of the Study for internal purposes, including, but not limited to, acknowledging the Investigator's work.

13.2 Advertising. Neither the Institution nor the Investigator shall issue to the public any information or statement through the press or any other media, including advertisements for the enrollment of Study Subjects, without the prior written permission of Cadila CRO and ethics committee and the review and approval of the IRB.

14. Indemnification and insurance:

14.1 Indemnification.

(d) Except as set forth below, Cadila CRO shall defend, indemnify and hold harmless the Institution, officers, agents, and employees, including the Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare personnel providing services to the Institution in connection with its conduct of the Study (collectively, the **"Institutional Indemnified Parties"**) from and against any and all liability, claim, loss, damages and expense (collectively, **"Losses"**) incurred by them in connection with any and all suits, investigations, claims or demands by or on behalf of Subjects taking part in the Study (or their dependents) against any Institutional Indemnified Party for personal injury (including death) to Subjects to the extent arising out of direct result of the intake or use of the Investigational Products, including (a) the administration of the Study Drug in accordance with this Agreement, the Protocol and any other written instructions of Cadila CRO or (b) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, or the use by Cadila CRO of the results of the Study, provided that, in each case (a) or (b), the Institution and the Investigator have (i) used reasonable medical judgment in the conduct of the Study (including the enrollment of Subjects for which participation in the Study is medically appropriate) and (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice.

(e) Notwithstanding anything contained herein to the contrary, the Cadila CRO and/or its directors, officers, employees, consultants and advisors shall not be liable to the Institution, officers, agents, and employees, including the Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare personnel, in any manner in whatsoever and howsoever arising under this Agreement:

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(i) for any special, non-compensatory, consequential, indirect, incidental loss, damage, including without limitation for loss of profits, loss of sales, loss of revenue and/or loss of use, regardless of the form of action, manner whether in contract, tort, negligence, strict liability, or otherwise except provided here in this Agreement under clause 'Indemnification';

(ii) arising out of or relating to the negligence, willful malfeasance or wrongful acts or omissions of any Institutional Indemnified Party, or by the negligence or failure of any Institutional Indemnified Party to comply with the provisions of this Agreement, the Protocol or any written instructions of Cadila CRO concerning the Study;

(iii) to the extent that such Loss arises out of or relates to the Investigator's or the Institution's negligence or failure to promptly report to Cadila CRO any significant or alarming developments that may occur during the Clinical Study, including any Subject adverse experiences or Serious Adverse Events (as both such terms are defined in the Protocol).

14.2 Reimbursement of Medical Expenses: Cadila CRO shall reimburse the Institution for the direct, reasonable and necessary medical expenses incurred by the Institution for the treatment of any personal injury that is a direct result of (a) the administration of the Study Drug in accordance with this Agreement, the Protocol and any other written instructions of Cadila CRO or (b) any performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Clinical Study if (i) the Institutional Indemnified Parties have complied with this Agreement, the Protocol and any written instructions of Cadila CRO concerning the Clinical Study and (ii) all the requirements of informed consent have been complied with in accordance with Section 5.2. Cadila CRO will not provide compensation for lost wages or for any other damages, expenses or losses, or for medical expenses that have been covered by a Subject's medical or other insurance, provided, however, Cadila CRO understands and agrees that Subject is not required to file an insurance claim. Cadila CRO shall ensure compensation over and above SAE management /reimbursement with the exceptions. Sections 14.1 and 14.2 shall not apply to any Loss:

15. Insurance:

15.1 The Cadila CRO will have an insurance policy for an appropriate amount adequate to cover the risks of its obligations under this agreement. A copy of such policy shall be provided to the institution on their request, if any. Policy will be used by the Party, for any personal/bodily injury suffered by the person involved in the study as specified under this Agreement.

16. Termination:

16.1 Right to Terminate or Suspend Clinical Study: The Clinical Study may be terminated or suspended by Cadila CRO immediately upon written notice to the other Parties on safety concerns or as otherwise required under the Applicable Laws. Further, Cadila CRO may terminate or suspend the Clinical Study if the Multi-Center Study is terminated or suspended.

16.2 Right to Terminate Agreement by Cadila CRO: Cadila CRO may suspend and/or terminate this Agreement, in its sole discretion, on ten (10) business days' advance written notice to the Institution and Investigator. The Cadila CRO or the Institution may terminate this Agreement in the event of material breach by the parties to this Agreement, provided that the written notice is explaining the nature of the default and an opportunity to cure such default within a period of 30 business days after the giving of

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notice. The Institution may terminate this Agreement, on written notice to Cadila CRO, if the Clinical Study is suspended or terminated and not recommenced within ninety (90) days.

16.3 Right to Terminate Agreement by Institute: The Institute can terminate the clinical study on the following reason:

(j) if the Principal Investigator becomes incapacitated or terminates his/her relationship with the Institution and a replacement suitable and agreeable to Cadila CRO cannot, after reasonable efforts by the Institution, be found;

(k) if Institution has indication of serious physical harm being suffered by any of the Trial Subjects at its site, it may immediately suspend enrollment of Trial Subjects at its site.

16.4 Transition upon Termination: Upon notice of termination of the Clinical Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into the Study and, at the discretion of Cadila CRO, shall: (a) terminate the Study with respect to the enrolled Subjects in an orderly and prompt manner, to the extent medically permissible, and pursuant to consultation with Cadila CRO's clinical monitor, including, without limitation, any required follow-up treatment with previously enrolled Subjects or (b) transfer the enrolled Subjects to another clinical site in accordance with Cadila CRO's instructions. Cadila CRO or its designee shall have the right to assume full control of the terminated Study and the Institution shall turn over all Study Documentation and materials in its possession associated with the Study, including all Work Product, Inventions and Materials, as expeditiously as possible, shall handle the Study and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol. Upon notice of suspension of the Study, the Institution shall immediately cease enrollment of Subjects into the Study. Cadila CRO shall reimburse Institution for all expenses incurred from such transition except for such transitions required due to an uncured breach of this Agreement by Institution.

16.5 Payment Owed: Except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution, upon termination of the Study or this Agreement, Cadila CRO shall, upon receipt of applicable invoices and other supporting documentation satisfactory to Cadila CRO: (a) reimburse the Institution for its reasonable and verifiable Study costs and reasonable un-cancelable Study costs or expenses incurred in connection with transfer of Subjects pursuant to Section 16.4 and (b) with respect to Subjects who have not completed the Study at the date of the termination, make payments to the Institution in accordance with Annexure I for work already performed in accordance with the Study.

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16.6. Final Accounting: Within thirty (30) days after the termination of this Agreement, each party will settle its account and the Institution shall deliver to Cadila CRO a final accounting of all Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and all reasonable direct costs incurred in connection with any transfer of the Study as agreed and mentioned in the payment schedule annexed herewith. Within thirty (30) days of delivery or receipt of the final accounting, either the Institution shall refund to Cadila CRO any excess amounts paid by Cadila CRO or Cadila CRO shall pay any additional amounts due to the Institution, as the case may be. Cadila CRO or its designee shall have the right for a period of two (2) years after the payment of any transfer costs to audit the Institution's books and records with respect to such accounting.

17. Miscellaneous:

17.1 Independent Contractor. In undertaking to perform the respective services hereunder, Cadila CRO, the Institution and the Investigator are doing so as independent contractors, and not as employees or agents of other Parties.

17.2 Assignment. No Party shall assign this Agreement or any rights or obligations hereunder without the prior written consent of the other Parties, except that Cadila CRO, without the consent of any other party hereto, may assign this Agreement and its rights and obligations hereunder (a) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, (b) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Drug or (c) to any direct or indirect affiliate of Cadila CRO.

17.3 Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law and if the rights or obligations of any party will not be materially and adversely affected: (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the parties. To the fullest extent permitted by applicable law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

17.4 Notices. Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, email or by facsimile (with transmission confirmed), addressed to the parties at the below mentioned address of the Parties:

If to Sponsor to:
Dr. Manjul Joshipura,
Address: Cadila Pharmaceuticals Ltd.,
1389, Trasad Road, Dholka,
Dist: Ahmedabad- 382225,
Gujarat, India

15/12/20

If to Investigator to:
Dr Kishan Ninama, Associate Professor
Department of Skin & VD
Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital
At & Po Piparia, Ta. Waghodia, Vadodara 391760

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If to the Institute:
Dr Chandramani B More
Registrar
Sumandeep Vidyapeeth an Institution Deemed to be University
At & Po Piparia, Ta. Waghodia, Vadodara 391760

If to the SMO:
Dr. Romita Gujar
RAV Research Private Limited,
2A/2,Shree Gokul CHS, Vrindaban Society
Thane (west) 400601, Maharashtra India

17.5 Business Communications.

The parties consent to receive communications sent via mail, e-mail and/or fax at the Investigator mailing address, e-mail address and fax number set forth in this agreement.

17.6 Entire Agreement. This Agreement, together with the appendices hereto constitute the entire agreement among the Parties hereto with respect to the subject matter of this Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is relying on the representations, warranties or covenants of other party as set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud; misrepresentation, gross negligence, willful misconduct or false statement.

17.7 Period of Performance. The performance of this Agreement shall be commenced from the Effective Date and shall continue valid and in full force till the completion of the Clinical Study or termination of the Clinical Study by Cadila CRO or termination of this Agreement, whichever is earlier.

17.8 Amendment. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.

17.9 Waiver. A party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

17.10 Inconsistency. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Clinical Study and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

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17.11 Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, the word "or" has the inclusive meaning represented by the phrase "and/or" and the term "including" or "includes" means including, without limiting the generality of any description preceding such term. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. A reference in this Agreement to a Section or Annexure is to the referenced Section or Annexure of this Agreement. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied.

17.12 Counterparts. This Agreement may be executed in two counterpart copies, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

17.13 Governing Law, Jurisdiction and Dispute Resolution. This agreement shall be governed by applicable laws of India and is subject to exclusive jurisdiction of the Courts Situated at Mumbai, India. Any dispute arising out of or in connection with this agreement, shall be first solved amicably by the Parties within 30 days of the dispute arises, failing which the same shall be referred to the sole arbitrator mutually decided by the Parties or each Party to nominate its Arbitrator and thereof; the two Arbitrator will nominate the Presiding Arbitrator, in accordance with Indian Arbitration and Conciliation Act 1996, its amendments and rules and regulations thereof. The seat and venue of arbitration will be at Mumbai,, India.

17.14 Survival Clauses. Clause 3 (Representations and Covenants), Clause 11 (Confidentiality), Clause 14 (Indemnification), Clause 17.13 (Governing Law, Jurisdiction and Dispute Resolution), shall survive termination or expiration of this Agreement for infinite period unless otherwise specifically provided in this Agreement, in addition to any other provisions that by their content are intended to survive the performance, termination, expiration or cancellation of this Agreement.

(Signature Page to Follow)

THIS AGREEMENT IS EXECUTED by the Parties through their authorized representatives as of the date first written above:

For: CADILA PHARMACEUTICALS LTD.	For: INSTITUTION
Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	Name: Dr Chandramani B More Designation: Registrar Place: Vadodara Date: 15/12/20
Name : Mr. Vinod Jain Designation : Chief Financial Controller	For INVESTIGATOR Name: Dr Kishan Ninama Designation: Associate Professor Place: ~~Navi Mumbai~~ Vadodara Date: 07/12/2020
Name: Mr. Sanjeev K Singh Designation: GM - Legal 24.10.20	For SMO Name: Dr. Romita Gujar Designation: Director Place: Thane Date: 10/Dec/2020

07/12/2020

FINANCIAL AGREEMENT

Sponsor Study No. : ADBG1910

Protocol Title : Multi-center, double-blind, randomized, placebo controlled, parallel-group study, comparing Adapalene and benzoyl peroxide gel, 0.3%/2.5% (Cadila Pharmaceuticals Limited) to Epiduo® Forte (Adapalene and benzoyl peroxide) gel, 0.3%/2.5%, Galderma Laboratories, l.p.) And both active treatments to a placebo control in the treatment of acne vulgaris.

Sponsor : Cadila Pharmaceuticals Ltd.

Cadila CRO on behalf of Sponsor offers to pay **Dr Kishan Ninama** (Principal Investigator) Department of Skin & VD, Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta. Waghodia, Vadodara 391760, India **(Institution) as** follows for the study under taken. **Cadila CRO** will make a maximum payment of Rs.25,000/- per completed patient to **Dr Kishan Ninama** on behalf of the Cadila Pharmaceutical. This per patient grant will take care of all the on-site expenses (administrative and clinical) and all the on-site Admissions and Investigations that are required by the Protocol as per the schedule mentioned therein.

Cadila CRO will make payment on monthly basis upon receiving bills or receipt for all the study procedures including payment to pateint for their trasportation.

Cadila CRO is expecting **Dr Kishan Ninama** to finish the enrollment of 30 to 40 subjects within six (6) months from the beginning of clinical trials for the Clinical Study. The enrollment is competitive had patient load will be redistrubuted to site where the recruitment is faster to achieve the largest sample size quickly.

In case the patient is not able to complete the study, the per patient grant will be paid to the PI depending upon the parameters as mentioned in the folowing Annexure I:

19/12/20

RIGHT

Annexure I

STUDY TITLE: A MULTI-CENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL-GROUP STUDY, COMPARING ADAPALENE AND BENZOYL PEROXIDE GEL, 0.3%/2.5% (CADILA PHARMACEUTICALS LIMITED) TO EPIDUO® FORTE (ADAPALENE AND BENZOYL PEROXIDE) GEL, 0.3%/2.5%, GALDERMA LABORATORIES, L.P.) AND BOTH ACTIVE TREATMENTS TO A PLACEBO CONTROL IN THE TREATMENT OF ACNE VULGARIS

Terms of Payment:

1. Fixed Cost as PI fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 25,000/- per patient upon achieving the below milestones.

Milestone	Payment
Screening - Visit 1	7000
Visit 2	6000
Visit 3	6000
Visit 4	6000

2. Maximum up to Rs. 10,000/-per patient will be paid to Site Coordinator as per the below milestones.

Milestone	Payment
Screening - Visit 1	2000
Visit 2	2000
Visit 3	2000
Visit 4	4000

3. Patient compensation will be provided Rs. 500/- per visit per patient.
4. Administrative cost (for stationary, courier, telephone, fax, internet) will be paid Rs. 10,000/- for entire study.
5. Study medications will be provided by sponsor. (As mentioned in protocol)
6. TDS will be deducted as per government policy.
7. As per new regulations, GST is applicable over and above of total budget.
8. Reimbursement of related Adverse Events/SAE medication management cost on actual as per DCGI Guidelines. In most situations where AE/SAE is prima facie unrelated, medical management cost will not be paid unless meeting all criteria of detailed DCGI guidelines.
9. Rs. 50,000/- will be given for archiving the documents for 15 years.
10. 30% of PI Fees will be paid to Institutional Head

Investigator has to complete below information:

CADILA PHARMACEUTICALS LIMITED

SUMANDEEP VIDYAPEETH

A. Payment Cheque required in favour of/payable to:
Research Cell Sumandeep Vidyapeeth
Account No.: 178802000000131
Bank Name: Indian Overseas Bank
IFSC Code: IOBA0001788

B. Address where payment Cheque would be sent:
Dr Kishan Ninama, Associate Professor
Department of Skin & VD
Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital
At & Po Piparia, Ta. Waghodia, Vadodara 391760

C. PAN Number or TAN Number, if applicable: **AAATK4485H**
GST No.: AAATK4485H1ZK

By signing this FINANCIAL AGREEMENT, **Cadila CRO, Ahmedabad**, **Principal Investigator** and **the SMO** agree to adhere to the terms and conditions mentioned in the CLINICAL TRIAL INVESTIGATOR's AGREEMENT.

For: CADILA PHARMACEUTICALS LTD. Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	For: INSTITUTION Name: Dr Chandramani B More Designation: Registrar Place: Vadodara Date: 15/12/20
Name : Mr. Vinod Jain Designation : Chief Financial Controller	For INVESTIGATOR Name: Dr Kishan Ninama Designation: Associate Professor Place: ~~Navi Mumbai~~ Vadodara Date: 07/12/2020
Name: Mr. Sanjeev K Singh Designation: GM - Legal 24.10.20	For SMO Name: Dr. Romita Gujar Designation: Director Place: Thane Date: 10 Dec 2020

07/12/2020

Attested CTC

30/11/2023

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