भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

ગુજરાત गुजरात GUJARAT ..... રૂ. ..... BU 869419

તારીખ: ..... માહે ..... સને ૨૦૧૯

નામ:

સરનામું: - 4 MAY 2019

શૈલેષકુમાર વાસુદેવભાઈ ત્રિવેદી

લા. નં. :- એસ. બી.- ૬૩/૧૯૮૬

અમદાવાદ-સીટી સીવીલ કોર્ટના સણંદી

લેનાર ની સહીX: કેતન.

CADILA HEALTHCARE LTD.
R & D CENTRE,
SURVEY NO. 396/403,
OPP. SARVOTAM HOTEL,
NR. NOVA PETROCHEMICALS,
VILLAGE : MORAIYA,
AHMEDABAD - 382 213

CLINICAL STUDY AGREEMENT

Among

1. **CADILA HEALTHCARE LIMITED**, a multinational pharmaceutical company incorporated under the laws of India, having its Registered Office at Zydus Towers, Satellite Cross Roads, Ahmedabad-380015, India (hereinafter referred to as **"the Sponsor"**)

2. **DR. JOSHI HARSHALKUMAR KAMLESHBHAI,** Assistant Professor, Dhiraj General Hospital, Sumandeep Vidhyapeeth, At & Po. Piparia. Ta. Waghodia, Dist Vadodara-391760, Gujarat, India (hereinafter referred to as **"Principal Investigator"**)

Attested CTC
29/11/2022.

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

SUMANDEEP VIDYAPEETH

3. **DHIRAJ GENERAL HOSPITAL,** Sumandeep Vidhyapeeth, At & Po. Piparia. Ta. Waghodia, Dist Vadodara-391760, Gujarat, India (hereinafter referred to as **"the Institution")**

CADILA PROJECT:

"A Phase 3, Multicenter, Multi-country, Open-label, Randomized, Active-controlled Clinical Trial to Evaluate the Efficacy and Safety of Desidustat Versus Darbepoetin for the Treatment of Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis. (CHL Trial No. DESI.18.001)"

This Clinical Study Agreement ("Agreement") is executed on **15th day of Jul, 2019** ("Effective Date") among Cadila Healthcare Limited, Zydus Towers, Satellite Cross Roads, Ahmedabad-380015, India; **Dr. Joshi Harshalkumar Kamleshbhai, Assistant Professor, Dhiraj General Hospital, Sumandeep Vidhyapeeth, At & Po. Piparia. Ta. Waghodia, Dist Vadodara-391760, Gujarat, India,** for the study entitled **"A Phase 3, Multicenter, Multi-country, Open-label, Randomized, Active-controlled Clinical Trial to Evaluate the Efficacy and Safety of Desidustat Versus Darbepoetin for the Treatment of Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis (CHL trial No. DESI.18.001)"** (Hereinafter referred to as **"the study"**).

This Agreement also covers any companion protocol(s) later developed and approved by all the Parties that are conducted concurrently with the protocol identified herein (collectively "Protocol") and that involve some or all the same subjects. The Sponsor and the Institution hereby declare that all the necessary permissions and licences required under the provisions of various acts and rules thereunder have been obtained for the performance of their respective obligations under this Agreement.

AND WHEREAS the Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study.

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

THE PARTIES AGREE AS FOLLOWS:

1. The Sponsor would like to test the tablet namely **DESIDUSTAT** which will be used in **anemic patients with Chronic Kidney Disease (CKD) who are not on Dialysis, aged 18 to 80 years at the time of enrollment in the study.** The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) will be obtained before the start of the study.

2. The Sponsors have approached the Investigator as they desire to perform the study in regards to the said drug in accordance with the Declaration of Helsinki, the Indian

Guidelines on Good Clinical Practices and Local Regulations and have accordingly finalized the Clinical Trial Protocol.

3. The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled namely **"A Phase 3, Multicenter, Multi-country, Open-label, Randomized, Active-controlled Clinical Trial to Evaluate the Efficacy and Safety of Desidustat Versus Darbepoetin for the Treatment of Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis (CHL trial No. DESI.18.001)".** All amendments and appendices have also been read and understood. The investigator agrees to the protocol and will perform the study in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices, and applicable laws, rules and regulations.

THE PARTIES AGREE AS FOLLOWS:

4. **Investigators and Research Staff**

4.1 **Principal Investigator:** The Study will be conducted by **Dr. Joshi Harshalkumar Kamleshbhai, Assistant Professor, Dhiraj General Hospital, Sumandeep Vidhyapeeth, At & Po. Piparia. Ta. Waghodia, Dist Vadodara-391760, Gujarat, India,** with registration number **G-27520;** the Principal Investigator. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub-investigators and research staff and the Institution.

4.2 **Sub-investigators and Research Staff:** Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub-investigators or research staff.

4.3 **Obligations:** Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is responsible to the Sponsor for compliance by Investigators, with the terms of this Agreement.

4.4 **No Substitution:** The Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from the Sponsor.

4.5 **Delegation of Duties by Principal Investigator:** The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical trials in India.

4.6 **Compliance with Institutional Policies:** The Principal Investigator will comply with the policies and procedures of the organization/institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify the Sponsor promptly of any conflict between the terms of

this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation

4.7 Audit: The Principal Investigator will make necessary arrangement for inspection of documents etc. by Sponsor's monitor, official of regulatory agency.

5. **Funding:** The conduct of the study will not impose any financial burden on the Principal Investigator or the Institution. The Sponsor declares to bear all the expenses pertaining to the conduct of the study.

   5.1 Financial Support for Clinical Trial: The details of the financial support to investigators and the budget sheet are attached in Annexure A hereunder:

6. **Protocol:** Investigator will conduct the Study in accordance with the Protocol, Indian GCP guidelines and applicable rules and regulations in India.

   6.1 Amendments: The Protocol may be modified only by a written Amendment, signed by both the Sponsor and the Principal Investigator.

   6.2 Emergency Amendments: If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify the Sponsor and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by execution of a written Amendment within 30 days.

   6.3 No Additional Research: No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

7. **Subject Enrolment:** Investigator has agreed agrees to enrol the subjects in the study as may be defined and decided by the Sponsor from time to time. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.

   7.1 Excess Enrolment: If Investigator enrols the maximum number of qualified subjects, the Sponsor may or may not invite Investigator to enrol additional subjects. However, the Principal Investigator shall not enrol more than maximum number without prior approval by the Sponsor.

   7.2 Failure to Enrol: If Investigator fails to enrol subjects at a rate adequate to meet the enrolment requirement, the SPONSOR shall be free to terminate the Study early (see Section 24, Termination).

8. **Study Conduct:** Investigator will conduct Study in accordance with the Protocol, the Sponsor's written instructions, Indian Good Clinical Practices (Indian GCP) guidelines and all applicable governmental laws, rules, and regulations.

   8.1 No Charge for Investigational Drug or Reimbursed Services: Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Clause 13.1,

Investigational Drug) or for any services reimbursed by the Sponsor under this Agreement.

9. **Independent Ethics Committee/Institutional Review Board:** Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a 'IRB') that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

10. **Study Disapproval:** If, through no fault of Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 24.1.1, Disapproval by IRB, below.

11. **Data Protection:** Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Cadila Healthcare Limited group of companies, to representatives and contractors working on behalf of the Sponsor group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause 12. The Principal Investigator shall be responsible for obtaining Sponsor's permission before publication or conference presentation of any Sponsors' data.

12. **Informed Consent and Authorization to Use and Disclose Health Information:**

    12.1 **Informed Consent:** Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow the Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 16).

13. **Adverse Events:** Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone, e-mail or facsimile. The Investigator shall, so far as is lawful, have full responsibility for the reporting of all serious and unexpected adverse events and/ or deaths to local regulatory authorities as per prevailing regulations. The

Sponsor has and will maintain during the Study, an insurance policy adequate to cover adverse events or injury to Study Subject(s) as a direct result of participation in the Study.

13.1 **Investigational Drug:** The Sponsor will provide Investigator with sufficient quantities of the investigational drug(s) needed to conduct the Study.

13.2 **Custody and Dispensing:** The Principal Investigator will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except sub-investigators or research staff. The Principal Investigator shall maintain the records of inventory of the Investigational drug.

13.3 **Use:** Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

13.4 **Ownership of Investigational drug:** Investigational drug remains the property of the Sponsor except for, and limited to, the use specified in the Protocol, the Sponsor grants Investigator no express or implied intellectual property rights in Investigational drug or in any methods of making or using the Sponsor's DRUG.

14. **Confidential Information:** During the course of the Study, Investigator may receive or generate information that is confidential to the Sponsor. Any information marked by the sponsor as confidential and provided to the investigator 1 year before the execution of this agreement will also be treated as confidential information.

14.1 **Definition:** Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

14.1.1 the Protocol,

14.1.2 the Investigator Brochure,

14.1.3 Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to

14.1.4 Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),

14.1.5 Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and

14.1.6 Any other information related to the Study, the Sponsor's DRUG, or The Sponsor technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2 **Exclusions:** Confidential Information does not include information that

14.2.1 is known or open to the public or otherwise in the public domain at the time of disclosure,

14.2.2 becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,

14.2.3 is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or

14.2.4 Is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 **Obligations of Confidentiality:** Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

14.3.1 Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.

14.3.2 Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 **Disclosure Required by Law:** If disclosure of Confidential Information to any party other than the IRB relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

14.4.1 Notifies the Sponsor in writing in 15 working days advance of the disclosure so as to allow the Sponsor to take legal action to protect its Confidential Information,

14.4.2 Discloses only that Confidential Information required complying with the legal requirement, and

14.4.3 Continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

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

14.6 **Survival of Obligations:** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the study and marketing of the drug.

14.7 **Return of Confidential Information:** If requested by the Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. **Study Data, Biological Samples and Study Records:**

15.1 **Study Data:** During the course of the Study, Investigator will collect and submit certain data to the Sponsor or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to the Sponsor or its agent within the reasonable time period.

SUMANDEEP VIDYAPEETH

15.1.1 **Ownership of Study Data:** Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), the Sponsor is the exclusive owner of all Study Data.

15.1.2 **Non-exclusive License:** The Sponsor grants Investigator no right to use study data for any purpose including internal research and/or education purpose.

15.1.3 **Data Management and statistical Analysis:** The Sponsor or its representative shall carry out the data management and statistical analysis. The Sponsor may consult and / or provide the Principal Investigator for interpretation during report writing.

15.1.4 **THE SPONSOR** is the exclusive owner of study data.

15.2 **Biological Samples:** If so specified in the Protocol, Investigator may collect and provide to the Sponsor or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomics, or biomarker testing ("Biological Samples").

15.2.1 **Use:** Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

15.2.2 **Analysis samples:** The Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.

15.2.3 **Ownership:** The Sponsor is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

15.3 **Study Records:** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

15.3.1 **Retention:** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 5 years after termination of the Study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor before destroying any Study Records after the required retention period. Investigator further agrees to permit the Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. **Monitoring, Inspections and Audits**

16.1 **Monitoring:** The Sponsor shall be entitled at its absolute discretion (and in such form as the Sponsor sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit the Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-

operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by the Sponsor will relieve the Investigator of any of its obligations hereunder.

16.2 **Inspections and Audits:** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. The Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

16.2.1 **Notification:** Investigator will notify the Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.

16.2.2 **Cooperation:** Investigator will cooperate with regulatory agency or the Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

16.2.3 **Resolution of Discrepancies:** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

16.2.4 **Inspection Findings and Responses:** Investigator will promptly forward to the Sponsor copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide. The Sponsor with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.

16.2.5 **Data Clarification Form:** The Sponsor may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the Principal Investigator or his nominee shall clarify within 7 working days.

16.2.6 **Study Conduct Evaluations:** The Sponsor or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor will use these evaluations solely for internal purposes.

17. **Inventions:**

17.1 **Notification:** If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the SPONSOR

17.2 **Assignment:** Investigator will assign all interest in any such Invention to the Sponsor, free of any obligation or consideration beyond that provided for in this Agreement.

17.3 **Assistance:** Investigator will provide reasonable assistance to the SPONSOR in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

18. **Publications:**

18.1 **Prepublication Review:** The Sponsor has no objection to publication by Investigator of any information collected or generated by Investigator, whether or not the results are favourable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Investigator will provide the Sponsor, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.

18.1.1 **Submission to the Sponsor:** Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation, etc.) to the Sponsor at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.

18.1.2 **Redaction of Confidential Information:** Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

19. **Debarment and Exclusion:** The Principal Investigator and Investigator each certify that it/s/he / she is not debarred and that it/s/he/she is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify the SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. **Use of Name:** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify the Principal Investigator and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. **Assignment and Delegation**

21.1 The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If the Sponsor authorizes delegation or subcontracting, Institution remains responsible to the Sponsor for the performance of all delegated duties

21.2 The Sponsor may not assign its rights or delegate its duties under this Agreement without written permission from the Principal Investigator. Any attempt to so assign or delegate is invalid. However, the SPONSOR may freely subcontract Study-related duties to an external provider upon advance notice to the Principal Investigator, and also may freely assign its rights or delegate its duties to any of the Sponsor affiliate. If the SPONSOR delegates or subcontracts any duties, the Sponsor remains responsible to the Principal Investigator for the performance of those duties.

21.3 **Affiliates:** As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the Sponsor

21.4 **Successors and Assigns:** This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. **Conflict with Attachments:** If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. **Indemnity:** Each Party upon receipt of prompt notice and opportunity to defend, shall indemnify and hold the other party harmless, and hereby forever releases and discharges the other Party from and against claims, demands, liabilities, damages and expenses including attorney fees arising out of the negligence of the indemnifying Party in connection with the work performed under this Agreement, provided, however, each party shall not be obligated to indemnify, defend or hold harmless the indemnified party to the extent the claim is caused by gross negligence or wilful misconduct of that party.

24. **Term and Termination:**

24.1 **Termination Conditions:** This Agreement terminates upon the earlier of any of, the following events:

24.1.1 **Disapproval by IRB:** If, through no fault of Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.

24.1.2 **Study Completion:** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by the Sponsor of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.

24.1.3 **Termination upon Notice:** The SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

24.1.4 **Immediate Termination by the Sponsor:** The Sponsor further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enrol subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the Sponsor 's opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.

24.1.5 **Termination upon Notice by Investigator:** The Principal Investigator may terminate the study, if the_Sponsor does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided

by registered mail to the SPONSOR fifteen days prior to termination and the Sponsor shall have fifteen days to cure its default.

24.1.6 **Immediate Termination by Investigator:** Investigator reserves the right to terminate the Study immediately upon notification to the SPONSOR if requested to do so by the responsible IRB or if such termination is required to protect the health of Study subjects.

24.2 **Payment upon Termination:** If the Study is terminated early in accordance with Section 24.1 Termination Conditions, above, the Sponsor will provide a termination payment equal to the amount owed for work already performed, less' payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 24.1.1, Disapproval by IRB, above), the Sponsor will reimburse Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by the Sponsor

24.3 **Return of Materials:** Unless the Sponsor instructs otherwise in writing, Investigator will promptly return all materials supplied by the Sponsor for Study conduct, including unused Investigational Drug, unused Case Report Forms, other study related material and any the Sponsor - supplied Equipment.

24.3.1 **Electronics Items**: On completion of the clinical study, the Investigator will return all the electronic items & their accessories in the working condition (if any) as provided by the Sponsor during the study.

24.4 **Treatment Code (Blinded Studies Only):** Upon request, the Sponsor will provide Investigator with a treatment assignment list that identifies, by subject number, the treatment that each Study subject received. Unless otherwise specified in the Protocol, the Sponsor will provide such treatment assignment information only after the Study is completed {or has been terminated and all data submitted) at all participating sites.

24.5 **Survival of Obligations:** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, and Debarment and Exclusion survive termination of this Agreement as does any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

25. **Modification:** Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

26. **Entire Agreement:** This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

27. This agreement shall be interpreted and enforced under the laws of India and the Courts of Ahmedabad shall have exclusive jurisdiction to resolve any dispute under this Agreement.

SUMANDEEP VIDYAPEETH

CLINICAL STUDY AGREEMENT

Executed by the parties:

SPONSOR:

Cadila Healthcare Limited

Mr. Mukund Thakkar
SVP, Legal

Dr. Sanjay Maroo
GM, Clinical R&D

INSTITUTION:

Name: Dr Chandramani B More,
The Registrar,
~~Dhiraj General Hospita~~l, Sumandeep Vidhyapeeth, (Can institution deemed to be University)
At & Po. Piparia. Ta. Waghodia,
Dist Vadodara-391760, Gujarat, India

Sign: _____ 04/09/19.

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

PRINCIPAL INVESTIGATOR:

Name: Dr. Joshi Harshalkumar Kamleshbhai,
Dhiraj General Hospital, Sumandeep Vidhyapeeth,
At & Po. Piparia. Ta. Waghodia,
Dist Vadodara-391760, Gujarat, India

Sign: _____ 4/9/19

SUMANDEEP VIDYAPEETH

CLINICAL STUDY AGREEMENT

ANNEXURE A: BUDGET SHEET AND OTHER EXPENSES:

Study Details	
Investigational drug	DESIDUSTAT
CHL Trial No.	DESI.18.001
Study Title:	A Phase 3, Multicenter, Multi-country, Open-label, Randomized, Active-controlled Clinical Trial to Evaluate the Efficacy and Safety of Desidustat Versus Darbepoetin for the Treatment of Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis.
Indication	Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis.
Phase:	III
Project Manager	Mr. Ranjan B Ranjesh
CRA	Ms. Brilina Patel
PI Name	Dr. Joshi Harshalkumar Kamleshbhai
Site Name & Address	Dhiraj General Hospital, Sumandeep Vidhyapeeth, At & Po. Piparia. Ta. Waghodia, Dist Vadodara-391760, Gujarat, India
Screen Failure Rate (%)	2:1 (33 %)

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CLINICAL STUDY AGREEMENT

Clinical Trial Budget		
No.	Particulars	Rate per Visit
A	Visit Expenses (Screening & Enrolment)	₹ 45,850.00
1	Visit 1 - Screening Visit	₹ 8,000.00
2	Visit 2 - Enrollment Visit	₹ 6,000.00
3	Visit 3	₹ 3,200.00
4	Visit 4	₹ 3,200.00
5	Visit 5	₹ 3,200.00
6	Visit 6	₹ 3,200.00
7	Visit 7	₹ 4,450.00
8	Visit 8	₹ 3,200.00
9	Visit 9	₹ 3,200.00
10	Visit 10 - End of Treatment	₹ 5,000.00
11	Visit 11 - Safety Follow Up	₹ 3,200.00
B	Additional Investigations	₹ 1,500.00
10	Additional Investigations (12-lead ECG)@ 500 each ECG	₹ 1,500.00
C	Other Expenses	₹ 14,670.00
13	Institutional Overhead @ 20%	₹ 9,170.00
14	Patient Reimbursement (500 Per Visit)	₹ 5,500.00
	Total (A+B+C) (D)	₹ 62,020.00
15	GST as per prevalent rate if applicable	

SUMANDEEP VIDYAPEETH

CLINICAL STUDY AGREEMENT

Terms & Conditions	
1	Reimbursement for screen failures will be at the amount indicated in the relevant screening section of the budget. To be eligible for reimbursement of screening visit, completed screening CRF pages must be submitted to Sponsor and any additional information, which may be requested by Sponsor to appropriately document the Study Participant screening procedures.
2	Final payments made will be only on the basis of SDV of subjects completed in the trial.
3	Major, disqualifying Protocol violations are not payable under this Agreement
4	No monthly payments will be processed if no patients are enrolled and / or screened within two months from date of study was conducted at site.
5	Reimbursement for discontinued or early termination Study Participants will be prorated based on the number of confirmed completed visits.
6	Last two invoices will be kept on hold untill final CSR is signed.
7	Any additional investigation(s) / Procedure(s) performed as per Principal Investigator's discretion will be reimbursed upon submission of hard copy of correct original invoice.
8	Any expense or cost incurred by Institution in performing this Agreement that is not specifically designated as reimbursable by Sponsor (including this Budget and Payment Schedule) is Institution's sole responsibility.
9	All amounts specified in this Agreement are in Indian Ruppes (INR).
10	Reimbursement of all expenses against monthly hard copy of correct invoices with proper supporting vouchers. Please note that tax invoices will not be processed unless they reference the Organisation name, Protocol number and Investigator. After verification & receipt of hard copy of correct tax invoice, reimbursement for tax invoices will be issued within 60 working days.
11	Any expense or cost incurred by Institution in performing this Agreement that is not specifically designated as reimbursable by Sponsor (including this Budget and Payment Schedule) is Institution's sole responsibility.
12	Tax deduction at source (TDS) as per the applicable regulations.
13	The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee):
14	Payee Name: Research Cell Sumandeep Vidyapeeth Payee Address: Research Cell, Sumandeep Vidyapeeth, At & Po Piparia, Ta. Waghodia, Vadodara 391760 Bank Name: Indian Overseas Bank Bank Account Name: Research Cell Sumandeep Vidyapeeth Bank Account Number: 178802000000131 IFSC Code:IOBA0001788
15	The Parties acknowledge that the designated Payee is authorised to receive all of the payments for the services performed under this Agreement. If the Institution is not the Payee, then the Payee's obligation to reimburse the Institution, if any, is determined by a separate agreement between Institution and Payee, which may involve different payment amounts and different payment intervals than the payments made by Local Sponsor to the Payee. Institution acknowledges that if Institution is not the Payee, Sponsor will not pay Institution even if the Payee fails to reimburse Institution.

Attested CTC

29/11/2022.

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