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Chennai.

06 NOV 2023

STATEMENT OF AGREEMENT

(Clinical Trial Agreement)

between

Dr. Nand Kishore

(Hereinafter referred to as the "Investigator")

And

Swami Rama Himalayan University, Dehradun

For its constituent college Himalayan Institute of Medical Sciences

(Hereinafter referred to as the "Institution")

Swami Rama Himalayan University
Director Research

Swami Rama Himalayan University
Registrar

and

iDD Research Solutions Pvt. Ltd.

(Hereinafter referred to as "CRO")

Protocol number:GB_LAB_001_21

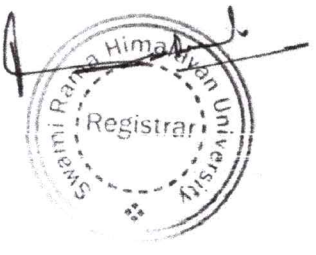
1 Introduction

a) CRO, a clinical research organization, is pleased that our discussions have resulted in your agreement to participate in and conduct this collaborative clinical research trial, titled "**A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy**"and "Gufic Biosciences, (the "Trial" and the "Sponsor" respectively)."

b)In order to make this Trial mutually rewarding, it is essential that we are in agreement with regard to the basic policies applicable to the Trial. Accordingly, this Clinical Trial Agreement in conjunction with Sponsor's protocol no. GB_LAB_001_21and A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy. which is incorporated by reference herein, will serve together as an agreement, delineating the terms and conditions applicable (the "Agreement"). Where there is a conflict between the terms of the Protocol and the Agreement, the terms of the Agreement shall prevail except where the conflict relates to medical, ethical or clinical issues in which case the Protocol shall prevail.

2 Trial Conduct

a.The scope and nature of the Trial and services to be performed by the Institution **at Himalayan Institute of Medical Sciences** should be in accordance with the Protocol.



b. As it is essential that the Trial is carried out exactly in accordance with the terms of the Protocol, each of the Institution and Investigator agrees to study the Protocol and satisfy themselves that they fully understand it and are able to conduct the Trial in the manner specified therein. Any change to the terms of this Agreement shall be valid only if the change is made by mutual written agreement of authorised representatives of all parties hereto. No changes or deviations to the Protocol should be implemented without agreement by the Sponsor and prior review and documented approval from the Ethics Committee ("EC"), unless to eliminate an immediate hazard to volunteers.

c. The Institution and Investigator shall be thoroughly familiar with the appropriate use of the Trial supplies (as defined below), as described in the Protocol, the current investigator's brochure, the product information leaflet, if any, and all information provided to them in connection with the Trial.

d. Accordingly the Institution and the Investigator each agree to carry out the Trial in accordance with:

- this Agreement;
- the Protocol;
- the provisions of the current applicable version of the World Medical Association's Declaration of Helsinki, applicable national' laws, regulations and guidelines including without limitation the New Drugs and Clinical Trials Rules, 2019, Ethical Guidelines for Biomedical Research on Human Subjects" laid down by Indian Council of Medical Research (ICMR), Indian GCP, and the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96)

3 Investigator

Institution's investigator, **(Dr.) Nand Kishore ("Investigator")** will be responsible for the direction and supervision of all Study efforts in accordance with the Protocol and this Agreement. Investigator and Institution shall provide all of the services contemplated herein through fully trained and competent Study Staff (as defined below) having a skill level appropriate for the tasks assigned to them and shall ensure that all Study Staff (as defined below) comply with the terms of this Agreement and the Protocol. "Study Staff" means (i) employees, officers, and directors of Institution, including without limitation the Investigator, and (ii) any agents, contractors or other third parties approved by Sponsor/CRO in writing in accordance with Article 15.In the event that Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of becoming aware of such departure by Investigator, provide written notice of such event to Sponsor/CRO. Any successor to Investigator must be approved, in writing, by Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Swami Rama Himalayan University
Registrar

Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to any applicable laws or regulations, or any applicable professional code of ethics.

Institution agrees to immediately inform Sponsor in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of Institution's knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder. Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Investigator's debarment and Investigator agrees to immediately inform Sponsor in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Investigator's debarment.

If information collected on the form changes during the course of the Study or within one year after the last subject has completed the Study as specified in the Protocol, Investigator and the other applicable Study Staff are required to inform Sponsor of such change.

4 Commencement and Duration

The Trial will commence following signature of this Agreement as soon as the Institution and the Investigator have received Ethics Committee (EC) approval and obtained a list of members and any national regulatory approval as appropriate has been obtained by Sponsor, Investigator and Institution. It is expected that a minimum of 25volunteers will be randomised to treatment at **Site name: Himalayan Institute of Medical Sciences**. Targeted subjects to the site will be increase or decrease upon the CRO or Sponsor discretion. At any time during the trial, if it becomes apparent that either Institution or Investigator will be unable to complete the Trial on schedule or enroll the number of volunteers specified, Institution or Investigator will notify CRO immediately to make appropriate alternative arrangements. Similarly, if CRO considers that the Institution's recruitment is unduly slow then the target number of volunteers may be reduced or the Trial terminated in accordance with section 15 below. Furthermore, if at any time during the course of the Trial the Institution and the Investigator have not reached their own enrolment target but the overall target of the Trial has been reached, Institution and Investigator will upon written request by Sponsor or CRO immediately stop recruitment. Sponsor will endeavor to provide Trial supplies in order to facilitate the agreed time lines; however, neither Investigator, Institution nor CRO will be held liable for any events that may result from delays that may occur.

5 Compensation

a. Sponsor will provide the financial support set out in the budget (Appendix A) and upon completion by Institution and Investigator of the Payment Invoice (Appendix B), for the conduct of the Trial in accordance with "National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, Indian GCP, Rule 122DAA New Drugs and Clinical Trials Rules, 2019, as applicable.

b. Each of Institution and Investigator will make all necessary notifications, filings and arrangements with the appropriate authorities in connection with their respective tax affairs and shall deal directly with such authorities and shall be exclusively responsible in respect of any liability for income, social, corporate or other taxes, which shall be incurred as a result of this Agreement.

6 Confidentiality, Data Protection and Intellectual Property

a. All information provided to the Investigator and the Institution either by the Sponsor or CRO or a third party for the purpose of carrying out the Trial and any data, information or results arising from the Trial will be considered confidential information and may only be disclosed to those who have a need to know such information for the sole purpose of administering the Trial. The confidential information shall remain confidential until it enters the public domain, through no fault of the Institution, Investigator or any other individual participating in the Trial. Confidentiality obligations set out above shall not apply in case the disclosure of any such confidential information is in compliance of any law in force or consequent upon any direction of any governmental, statutory authority or a court of law or tribunal. This clause shall survive the termination of this Agreement.

b. In accordance with Clause 9, Institution and Investigator will obtain the consent authorization document of each Trial subject to the holding and transfer of their data to countries other than their own, to countries that may not have the same level of data protection, as within their own country.

c. The Sponsor will process, use or transfer any personal information received from either the Trial subject or any individual involved in the Trial in accordance with any applicable data protection laws. Sponsor shall require that any party to whom sponsor discloses Health Information ("Recipient") agrees to use and disclose the Health Information only as permitted in the Authorization Documents and in accordance with all applicable laws and regulations. The Authorization Documents will not authorize the sponsor or any Recipient to use Health Information to recruit research subjects to additional studies, to advertise additional studies or products or to perform marketing or marketing research.

d. All documents, Protocols, data, know-how, methods, operations, formulas, confidential information and materials provided to the Institution and/or Investigator pursuant to this Agreement are and shall remain Sponsor's property. The Institution and the Investigator agree that case report forms or CRFs, the Final Report and other results of the Trial, if any, together with any patents, patent applications and other like forms of protection, database rights, registered and unregistered design rights, copyrights and rights in unpatented technical, intellectual property rights and other information not in the public domain which may subsist in any part of the world ("Intellectual Property") subsisting in or capable of subsisting in or otherwise protecting or capable of protecting any of the foregoing matters shall also be owned by Sponsor. The Institution and the Investigator shall ensure that all individuals working on the Trial, including the Investigator have assigned to Sponsor or have a legal obligation to disclose and assign to Sponsor all their rights to any of the Intellectual Property.

e. Neither CRO nor Sponsor shall transfer to Institution and Investigator by operation of this

Swami Rama Himalayan University Director Research

Swami Rama Himalayan University Registrar