తెలంగాణ తెలంగాణా TELANGANA

M. Sineesha.
BD 264314

Tran Id: **240130185426648978**
Date: **30 JAN 2024, 06:56 PM**
Purchased By:
AZIZUDDIN MOHAMMAD
S/o VASIUDDIN MOHAMMAD
R/o HYDERABAD
For Whom
HETERO BIOPHARMA LIMITED

M.SIREESHA
LICENSED STAMP VENDOR
Lic. No. 15-10-015/2017
Ren.No. 15-10-056/2023
FLAT15,BLOCK 5,KENDRIYA VIHAR,
MAYURINAGAR,MIYAPUR,
SERILINGAMPALLY MANDAL,
RANGAREDDY DISTRICT
Ph 9441885384

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("The Agreement") is made and executed **15/04/2024** by and between

Hetero Biopharma Limited a company incorporated under the Companies Act 2013 with Corporate Identification No. U24290TG2016PLC111946 and having its registered office at **7-2-A2, Hetero Corporate, Industrial Estate Sanathnagar I.E., Hyderabad-500018, Telangana State, India**, (hereinafter referred to as "**SPONSOR**", which expression unless repugnant to the subject or context therein shall mean and include its assignees, affiliates, employees, subsidiaries, nominees, agents and successors-in-interest) of the ONE PART

DS SSinha

Swami Rama Himalayan University Director Research

AND

Dr. Ankit Batra (MCI ID No: Tamil Nadu Medical Council - 158795), Consultant at Himalayan Institute of Medical Sciences (a constituent academic unit of Swami Rama Himalayan University), Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand- 248016, India and hereinafter referred to as the "**PRINCIPAL INVESTIGATOR**" (which expression unless repugnant to the subject or context therein shall mean and include his/ her heirs, executors and successors-in-interest) of the SECOND PART,

AND

Swami Rama Himalayan University (For its constituent academic unit Himalayan Institute of Medical Sciences) located at Swami Ram Nagar, Jolly Grant, Dehradun - 248 016, Uttarakhand, India. Hereinafter referred to as the "**INSTITUTION**" (which expression unless repugnant to the subject or context therein shall mean and include its heirs, executors and successors-in-interest) of the THIRD PART,

"SPONSOR", "PRINCIPAL INVESTIGATOR" and "INSTITUTION" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

WHEREAS

The SPONSOR is conducting a clinical trial entitled, Study title: **A Phase IV Multi-Centric, Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero-Trastuzumab in Female Patients with HER2+ Breast Cancer** (Annexure II) as permitted by the Drugs Controller General of India (DCGI) vide their approval letter dated **18/04/2023** ("the Study / Clinical Trial")

Vide Undertaking letter dated **30/06/2023** issued by the PRINCIPAL INVESTIGATOR, the PRINCIPAL INVESTIGATOR agreed to conduct the aforesaid Clinical Trial at **Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand- 248016, India** in Female Patients with HER2+ Breast Cancer.

A. The SPONSOR is the owner of the Clinical Trial Protocol (as defined hereinafter) and is interested in carrying out the said Clinical Trial, through the PRINCIPAL INVESTIGATOR.

DS SSinha

B. PRINCIPAL INVESTIGATOR is a qualified and experienced professional in conducting the Study.

C. The INSTITUTION is equipped and qualified to undertake the Study.

D. INSTITUTION and PRINCIPAL INVESTIGATOR have agreed to perform the Study on the terms and conditions hereinafter set forth.

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:

1.0 Term: The validity of the agreement is for a period of four years from the date of the Agreement or the completion of the Clinical Trial (approx. 24 months from the date of this Agreement), whichever is earlier.

2.0 Institutional Ethics Committee (IEC): Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IEC throughout its conduct. Sponsor shall not interfere in any IEC procedures. If IEC need any assistance from Sponsor, then Sponsor shall promptly give its assistance to IEC.

3.0 Study Disapproval: If, through no fault of Investigator, the Study is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Investigator.

4.0 The PRINCIPAL INVESTIGATOR will conduct the Clinical Trial strictly as per Protocol No.: HCR/IV/TRUMAB/05/2022 (Annexure II) ("Clinical Trial Protocol") and as approved by the Institutional Ethics Committee (IEC) in accordance with applicable regulatory requirements.

4.1 The Principal Investigator will comply with the policies and procedures of the institution 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.

DS SSinha

4.2 The PRINCIPAL INVESTIGATOR confirms that he / she has studied and understood the Clinical Trial Protocol and has agreed to conduct the Clinical Trial according to the guidelines prescribed by the DCGI.

4.3 The PRINCIPAL INVESTIGATOR hereunder shall perform the Study at the INSTITUTION mentioned in the aforementioned INVESTIGATOR UNDERTAKING and he/she shall be acting as the Collaborators if applicable, in the conduct of the Study and agree to be bound by the terms of this Agreement.

4.4 The PRINCIPAL INVESTIGATOR further represents, warrants and covenants that the PRINCIPAL INVESTIGATOR is and at all times, during the Term of this Agreement, he/she shall be:

a. In good professional standing,
b. In possession of all requisite professional licenses,
c. Fully qualified to conduct the Study and to act as the PRINCIPAL INVESTIGATOR under the Agreement,
d. Fully experienced and knowledgeable with respect to all matters pertaining to the study, and
e. Responsible for the supervision of all persons who may assist the PRINCIPAL INVESTIGATOR or otherwise be engaged in the study.

4.5 The PRINCIPAL INVESTIGATOR shall be responsible for the performance of the study as per the highest standards of medical and clinical research practices. Prior to commencing the Study, the PRINCIPAL INVESTIGATOR shall require, and each Collaborator engaged in the Study to complete and return to SPONSOR the Disclosure of Financial Interests and Arrangements, if any, in the Study.

4.6 The PRINCIPAL INVESTIGATOR and INSTITUTION shall notify to the SPONSOR immediately by telephone and email / facsimile if the DCGI, or any other governmental or regulatory authority in India requests permission to or does inspect the PRINCIPAL INVESTIGATOR and INSTITUTION's facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the PRINCIPAL INVESTIGATOR and INSTITUTION receives, obtains, or generates pursuant to any such Study.

DS SSinha

4.7 The PRINCIPAL INVESTIGATOR agrees to use his / her professional expertise to perform the Study in accordance with the Protocol and the terms and conditions of this Agreement. In the event SPONSOR does not approve, SPONSOR may terminate this Agreement in accordance with the Termination section below and INSTITUTION shall take all necessary steps to effectuate such termination.

4.8 The PRINCIPAL INVESTIGATOR agrees to ensure that no subject in this Study may participate concurrently in any ancillary study (technique, procedure, questionnaire or observation other than those set forth in the Protocol) without prior written approval in writing from SPONSOR. In the event that SPONSOR approves such participation in any ancillary study, the PRINCIPAL INVESTIGATOR agree that the ancillary study will be conducted in accordance with all applicable Laws, Rules and Regulations, including but not limited to Schedule Y (as amendment up-to-date) to Drugs & Cosmetics Rule 1945 and other applicable rules including The New Drugs and Clinical Trials Rules 2019 under Drugs & Cosmetics Act 1940, Guidelines of Indian Council for Medical Research, India Good Clinical Practice of the Central Drugs Standards Control Organization, ICH Guidance for Good Clinical Practice (as amendment up-to-date), Declaration of Helsinki. PRINCIPAL INVESTIGATOR agrees to provide SPONSOR periodically and in a timely manner during the term of this Agreement with all Clinical Trial results and other data collected as per the Protocol on properly completed (written or electronic) Case Record Forms.

4.9 PRINCIPAL INVESTIGATOR should prior inform the SPONSOR preferably before a month if planning to move out of the Study for any unforeseen reasons, and the PRINCIPAL INVESTIGATOR / INSTITUTION is responsible for identifying a suitable replacement in case where the PRINCIPAL INVESTIGATOR change happens in the Study. Prior approval should be obtained from the SPONSOR for all such changes and should be as per GCP and applicable regulatory requirements.

4.10 PRINCIPAL INVESTIGATOR agrees to report to SPONSOR all Serious Adverse Events (SAEs) and important medical events, as identified in the protocol, affecting any trial subject in the Clinical trial as per applicable regulatory guidelines (including but not limited to schedule Y guidelines and New Drugs and clinical trials rule 2019).

DS SSinha

Swami Rama Himalayan University Director Research