IN-GJ009900194418 37X

INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

सत्यमेव जयते

Certificate No.	:	**IN-GJ009900194418 37X**
Certificate Issued Date	:	23-Apr-2025 11:19 AM
Account Reference	:	IMPACC (SV)/ gj13334504/ GULBAI TEKRA/ GJ-AH
Unique Doc. Reference	:	SUBIN-GJGJ13334504114555981894 88X
Purchased by	:	CLIANTHA RESEARCH LIMITED
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CLIANTHA RESEARCH LIMITED
Second Party	:	HIMALAYAN INSTITUTE OF MEDICAL SCIENCE
Stamp Duty Paid By	:	CLIANTHA RESEARCH LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

Swami Rama Himalayan University Director Research

KV CLINICAL RESEARCH PVT. LTD. K V C R

Shri Jodia Ahmedabad STAMP VENDER

IN-GJ009900194418 37X

PR 0004682800

Registrar

Dr. RESHMA KAUSHIK
Professor & Head
Department of Medicine
H.I.M.S., Dehradun
Regn. No. UMC-2314

StatutoryAlert:

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સૂચના

- આ ઈ-સ્ટેમ્પ પ્રમાણપત્રની વિગતો www.shcilestamp.com દ્વારા અથવા સ્ટોક હોલ્ડિંગની "ઈસ્ટેમ્પિંગ" મોબાઈલ એપ્લિકેશન અથવા સ્ટોક હોલ્ડિંગની શાખા / કેન્દ્ર (જેની વિગતો www.stockholding.com પર ઉપલબ્ધ છે) પર જઈ ને ચકાસી શકાય છે.
- આ પ્રમાણપત્રમાં કરેલ કોઈપણ ફેરફાર અમાન્ય છે અને તે ફોજદારી ગુનો બને છે.
- આ ઈ-સ્ટેમ્પ પ્રમાણપત્રમાં કોઈપણ વિસંગતતા જણાય તો સ્ટોક હોલ્ડિંગની શાખા / કેન્દ્ર પર સંપર્ક કરવો.
- ઈ-સ્ટેમ્પિંગ સંબધિત જાણકારી માટે અમને estamp.ahmedabad@stockholding.com પર ઈ-મેઈલ કરવો અથવા અમારી શાખા / કેન્દ્ર ની મુલાકાત લેવી.

CLINICAL TRIAL AGREEMENT

PROTOCOL NO.: LPS17348

This Clinical Trial Agreement (the **"Agreement"**) is entered into on the 09th day of Jul, 2025 (the **"Effective Date"**) by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its registered office at Cliantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad - 382 210 (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its assignees and successors-in-interest)

AND

DR. RESHMA KAUSHIK, whose principal place of work is at Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Department of General Medicine, Jolly Grant, Dehradun – 248016, Uttarakhand, India (hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his/ her successors and permitted assigns)

AND

SWAMI RAMA HIMALAYAN UNIVERSITY (SRHU), a University established under section 2(f) of UGC Act and enacted vide Uttarakhand Act, having its registered office at Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand- 248016, through its Registrar, Commander Challa Venkateswar (Retd.), for its constituent unit, **HIMALAYAN INSTITUTE OF MEDICAL SCIENCES**, located at, Swami Rama Himalayan University, Department of General Medicine, Jolly Grant, Dehradun – 248016, Uttarakhand, India (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest)

AND

KV CLINICAL RESEARCH PVT LTD, located at, Office 617, Golden Trade Center, New Rajendra Nagar, Raipur-492001, Chhattisgarh, India (hereinafter referred to as the **"Site Management Organization/ SMO"** which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest)

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

WHEREAS, CRO has been contracted by Sanofi India Limited ("Sponsor") and CRO is authorized by the Sponsor to enter into the agreement on its behalf and has undertaken to abide by all the terms and condition of this Agreement. Authority letter is attached as annexure - 1 with this Agreement. having its principal/registered

Dr. RESHMA KAUSH
Professor & Head
Department of Medici
H.I.M.S., Dehradun
Reg.No.UKMC-2215

business address, Sanofi House, C.T.S. No. 117/B, L&T Business Park, Saki Vihar Road, Powai, Mumbai, Maharashtra, 400 072, India to perform one or more of Sponsor study related duties and functions for the clinical trial entitled as "A Phase IV, open label, clinical trial to assess safety and efficacy of Fexofenadine HCl + pseudoephedrine HCl fixed dose combination in Indian participants with allergic rhinitis (AR) who are 12 years and above (FAST trial)." ("Study") according to Protocol Number **LPS17348** ("Protocol") including any subsequent duly authorized amendments and which is hereby incorporated by reference; and

WHEREAS, SMO is a site management organization engaged in the business of managing services provided by its affiliated clinical research institutions and clinical investigators regarding the conduct of clinical research;

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

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

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

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

1. THE STUDY AND THE PROTOCOL

A. The Study of Allegra-D (the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. LPS17348 entitled A Phase IV, open label, clinical trial to assess safety and efficacy of Fexofenadine HCl + pseudoephedrine HCl fixed dose combination in Indian participants with allergic rhinitis (AR) who are 12 years and above (FAST trial) (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of Sponsor by the CRO.

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

Dr. Rama Himalayan University Registrar

DR. RESHMA KAUSHIK Professor & Head Department of Medicine H.I.M.S., Dehradun Reg.No.UKMC-2215

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

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

D. The SMO represents and warrants that it has the necessary experience and expertise to provide the services under this Agreement and that it shall use all commercially reasonable best efforts to perform the required services efficiently, hereunder.

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

F. Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an Ethics Committee / Institutional Review Board ("IRB") that complies with the requirements of Drug Controller General of India and GSR 227 (E) and applicable regulatory requirements. Principal Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct. Sponsor shall not interfere in any IRB procedures. If IRB need any assistance from Sponsor, then Sponsor shall promptly give its assistance to IRB. If the Study is disapproved by the IRB, this Agreement will immediately terminate.

Swami Rama Himalayan University Director Research

Swami Rama Himalayan University Registrar

CLANTHA RESEARCH LIMITED AHMEDABAD

KV CLINICAL RESEARCH PVT. LTD. KVCR

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