सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/24/000069

To,

M/s Klinera Global Services,
801, Neelkanth Corporate Park, Opp Vidyavihar Station,
Vidyavihar (West) Vidyavihar (India) - 400086.

Sir,

With reference to your application No. GCT/CT04/FF/2024/43308 dated 09/05/2024 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING THE SAFETY AND EFFICACY OF EFRUXIFERMIN IN SUBJECTS WITH COMPENSATED CIRRHOSIS DUE TO NONALCOHOLIC STEATOHEPATITIS (NASH)/METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH)" Protocol no: AK-US-001-0106, Version no. Original dated 19/Mar/2024 with a total of up-to 115 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

(i) **Human biological samples i.e. Blood serum, blood plasma, urine and liver biopsy tissue sample related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO**

(ii) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;

(iii) where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(iv) in case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(v) the Central Licencing Authority shall be informed about the approval granted by the

Ethics Committee within a period of fifteen working days of the grant of such approval;

(vi) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

(vii) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(viii) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(ix) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

(x) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

(xi) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

(xii) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

(xiii) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

(xiv) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

(xv) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

(xvi) the laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(xvii) the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xix) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(xx) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing Authority
Stamp

FORM CT-06

(See rules 22,25,26,29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

1. The Central Licensing Authority hereby permits **M/s. Klinera Global Services, 801, Neelkanth Corporate Park, Opp Vidyavihar Station, Vidyavihar (West) Vidyavihar (India) - 400086** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no: AK-US-001-0106, Version no. Original dated 19/Mar/2024** in the below mentioned clinical trial sites [As per Annexure].

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in Part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date _____

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)&
Central Licensing Authority
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Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Efruxifermin (EFX)
Therapeutic class:	Long Acting FGF21 Analog
Dosage form:	Lyophilized powder for solution for injection
Composition:	Efruxifermin(EFX) =50.0000 milligram (mg) U.S.P., Ph.Eur Active
Indications:	Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH)/Metabolic Dysfunction-associated Steatohepatitis (MASH)

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Centre for clinical research, JCMLRI, Indian Institute of Liver and Digestive Sciences campus, Sitala east, Sonarpur, Kolkata - 700150, West Bengal, India	Human Research Ethics Committee, Indian Institute of Liver and Digestive Science (HREC,IILDS) Sitala East, Sonarpur, Kolkata-700150, West Bengal, India ECR/1568/Inst/WB/2021	Dr. Abhijit Chowdhury
2.	PGIMER, Nehru Hospital Extension Block (NHEB), Ground floor, Room no-36, Sector 12, Chandigarh - 160012, India	Institutional Ethics Committee, PGIMER, Research 'B' block, 6thfloor, Chandigarh –160012, India ECR/25/Inst/CH/2013/RR-20	Dr. Ajay Duseja
3.	Gleneagles Hospital, 6-1-1070/1 to 4, Lakdi-ka-pul, Hyderabad -500 004, Telangana, India	Institutional ethics Committee Global Gleneagles Hospital, 6-1-1070/1 to 4, Lakdi-ka-pul, Hyderabad -500 004, Telangana, India ECR/158/Inst/AP/2013/RR-19	Dr. Chandan Kumar
4.	Institute of Medical Sciences, Department of gastroenterology, Banaras Hindu University, Varanasi-221005, Uttar Pradesh, India	Institutional Ethics Committee, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, Uttar Pradesh, India ECR/526/Inst/UP/2014/RR-20	Dr. Dawesh Prakash Yadav
5.	Samvedna Hospital, B-27/88-G, New Colony, Ravindrapuri, Varanasi - 221005, Uttar Pradesh, India	Samvedna Hospital Ethics Committee, Samvedna Hospital, B-27/88-G, New Colony, Ravindrapuri, Varanasi -221005, Uttar Pradesh, India ECR/45/Inst/UP/2013/RR-20	Dr. Hemant Gupta
6.	IPGME&R and SSKM Hospital, 244, A.J.C Bose Road, Kolkata -700020, West Bengal, India	IPGME&R Research Oversight Committee, IPGME&R, 244, A.J.C Bose Road, Kolkata - 700020, West Bengal, India ECR/35/Inst/WB/2013/RR-19	Dr Kausik Das

7.	Sterling Hospital, Opp. Inox, Race Course circle, Vadodara -390007 Gujarat, India	Sterling Ethics Committee, Sterling Hospital, 4thfloor (Phase-I), Opp. Inox, Race Course circle, Vadodara -390007 Gujarat, India ECR/582/Inst/GJ/2014/RR-20	Dr. Pankaj Jain
8.	Vishwaraj Hospital, Near Loni Railway station Loni Kalbhor, Solapur -Pune Highway, Pune -412201, Maharashtra, India	Institutional Ethics Committee, MAEER's Vishwaraj Hospital, Gate no. 499, Kadamwakwasti, Solapur road, Loni Kalbhor, Pune –412201, Maharashtra, India ECR/1138/Inst/MH/2018/RR-21	Dr. Kiran Shinde
9.	Sir Gangaram Hospital, Institute of Liver, Gastroenterology & Pancreatico-Biliary Sciences Rajinder Nagar, New Delhi - 110060, India	Ethics Committee Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi 110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Shivam Khare
10.	Government Medical college PO, Department of Medical Gastroenterology, Superspeciality block, Thiruvanathpuram-695011, Kerala, India	Human Ethics Committee Government Medical College Medical College PO Thiruvananthapuram, Thiruvananthapuram-695011, Kerala, India ECR/370/Inst/Ker/2013/RR-20	Dr. Krishnadas Devadas
11.	SIDS Hospital & Research centre, A unit of SIDS health care private limited, Off ring road, Near shell petrol pump, Ring road-sosyo circle lane, Surat-395002, Gujarat, India	Surat Institute of Digestive Sciences Ethics Committee, SIDS Hospital & Research centre, A unit of SIDS Healthcare Private Limited, J J Empire Building & Tapi Villa Building, Vijay Nagar Gate no-3, Besides Nirman Bhavan, Opposite, Gandhi College, Majura Gate, Ring Road, Surat-395002, Gujarat, India ECR/813/Inst/GJ/2016/RR-19	Dr. Mayank Kabrawala
12.	BAPS PramukhSwami Hospital, Shri Pramukh Swami Maharaj Marg, Adajan, Surat -395009 Gujarat, India	Institutional Ethics Committee BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajan Cross Road, Adajan, Surat-395009, Gujarat, India ECR/639/Inst/GJ/2014/RR-20	Dr. Parshottam Koradia

13.	Kothia Hospital, Nikol Gam Rd, Near torrent power, Uttam Nagar, Thakkarbapanagar, Ahmedabad-380038, Gujarat, India	Sangini Hospital Ethics Committee, Sangini Hospital, First Floor, Santorini Square, B/h Abhishree Complex, Opp. Star Bazar, Nr. Jodhpur Cross Road, Satellite, Ahmedabad –380015, Gujarat, India. ECR/147/Inst/GJ/2013/RR-19	Dr. Parth Shah
14.	Medical College and Hospital, 88 College Street, Kolkata -700073, West Bengal, India	Institutional Ethics Committee for Human Research Medical College And Hospital 88 College Street Kolkata-700073, West Bengal, India ECR/287/Inst/WB/2013/RR-19	Dr. Saubhik Ghosh
15.	SMS Super Speciality Hospital, Department of Gastroenterology Vivekanand Marg, C-Scheme, Jaipur –302004, Rajasthan, India	Ethics Committee, SMS Medical College and attached Hospitals, JLN Marg, Jaipur -302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-19	Dr. Sudhir Maharshi
16.	SR Kalla Memorial Gastro and General Hospital, 78-79, Dhuleshwar Garden, behind HSBC bank, Sardar Patel Marg, C-Scheme, Jaipur -302001, Rajasthan, India	SR Kalla Memorial Ethical Committee for Human Research, SR Kalla Memorial Gastro and General Hospital. 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur -302001, Rajasthan, India ECR/8/Inst/Raj/2013/RR-19	Dr. Mukesh Kalla
17.	All India Institution of Medical Sciences, Room no. 127, First floor, Old OT Block, AIIMS Ansari nagar, Delhi –110029, Delhi, India	Institutional Ethics Committee,All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital, Ansari Nagar, New Delhi-110029, Delhi, India ECR/538/Inst/DL/2014/RR-20	Dr. Shalimar
18.	Institute of Liver and Biliary Sciences, D-1, Vasant Kunj, New Delhi, Delhi 110070, Delhi, India	Institutional Ethics Committee Institute of Liver and Biliary sciences D-1, Vasant Kunj New Delhi South DelhiDelhi-110070, India ECR/67/Inst/DL/2013/RR-19	Dr. Shivkumar Sarin

19.	Midas Hospital,392, Behind Empress Palace, Opp Singh Saab Dhaba, Wardha Road, Parsodi, Nagpur-441108, Maharashtra, India	Institutional Ethics Committee, Midas Multispeciality Hospital Pvt. Ltd., 5thfloor, Midas Height, 07 Central Bazar road, Nagpur - 440010, Maharashtra, India ECR/494/Inst/MH/2014/RR-20	Dr. Shrikant Mukewar
20.	All India Institute of Medical Science, Department of Gastroenterology, Rishikesh -249203, Uttarakhand, India	Ethics Committee relating to Clinical Trial, All India Institute Of Medical Sciences, Rishikesh, Virbhadra Marg, Pashulok, Rishikesh, Dehradun, Uttarakhand –249203, India ECR/736/Inst/UK/2015/RR-21	Dr. Rohit Gupta
21.	Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Head, WHO Collaborating Center for Viral Hepatitis Raebareli Road, Lucknow, -226014, Uttar Pradesh, India	Institutional Ethics Committee Sanjay Gandhi Post Graduate Institute of Medial Sciences, Raebareli Road, Lucknow, Uttar Pradesh, India ECR/16/Inst/UP/2013/RR-20	Dr. Amit Goel
22.	Seth G.S Medical College and KEM Hospital, Department of Gastroenterology, MS Building, 9th Floor, Ward 32A, Parel, Mumbai-400012, Maharashtra, India	Institutional Ethics Committee(IEC), Seth G.S Medical College and KEM Hospital, Ground Floor, New UG/PG Hostel Building, S.S Rao Marg, Gate No 7, Parel, Mumbai-400012, Maharashtra, India ECR/229/Inst/MH/2013/RR-19	Dr. Arun Vaidya
23.	Gastroplus Hospital, D-Block, 3rd Floor, Galaxy Bazaar, Sunrise Park Road, Vastrapur, Ahmedabad - 380054, Gujarat, India	Gastroplus Ethics Committee, D-Block, 3rd Floor, Galaxy Bazaar, Sunrise Park, Vastrapur, Ahmedabad -380054, Gujarat, India ECR/1207/Inst/GJ/2019/RR-22	Dr. Ravindra Ghaadhe
24.	Inamdar Multispeciality Hospital CIMET's Inamdar Multispeciality Hospital. S.No. I 5, Fatima Nagar, Wanawadi. Pune -411040, Maharashtra. India	Ethics committee Inamdar Multispeciality Hospital CIMET's Inamdar Multispeciality Hospital. S.No. I 5, Fatima Nagar, Wanawadi. Pune -411040, Maharashtra. India ECR/354/Inst/MH/2013/RR-20	Dr. Ksheetij Kothari

25.	Department of Gastroenterology, ABVIMS & Dr. RML Hospital, Baba Kharak Singh Marg, New Delhi-110001, Delhi, India	Institutional Ethics Committee (IEC), ABVIMS & Dr. RML Hospital, Baba Kharak Singh Marg, New Delhi-110001, Delhi, India ECR/78/Inst/DL/2013/RR-19	Dr. Vaishali Bharadwaj

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