



File No. CT/24/000109

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/2024/45087 dated 29/08/2024 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Miricorilant in Adult Patients with Nonalcoholic Steatohepatitis/Metabolic Dysfunction-Associated Steatohepatitis (MONARCH)” Protocol no: CORT118335-862, amendment 2 dated 23-May-2024 with a total of up-to 125 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. Whole Blood, 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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,

(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: CORT118335-862, amendment 2 dated 23-May-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 _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)&
Central Licensing Authority
Stamp

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	Miricorilant
Therapeutic class:	Selective modulator of the glucocorticoid receptor
Dosage form:	Tablets
Composition:	Miricorilant =50.0000 milligram (mg) Active
Indications:	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.	SMS-Super Speciality hospital, 10-9, Vivekanand Marg, Panch Batti, Sangram Colony, Ashok Nagar, Jaipur, Rajasthan 302007, India	The Ethics Committee SMS Medical Collage and Attached Hospital first floor, Dhanvantri OPD block, SMS hospital, J.L.N.Marg, Jaipur-302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-19	Dr. Mukesh Kumar Jain
2.	Centre for Clinical Research -John C. Martin Centre for Liver Research and Innovations, Indian Institute of Liver and Digestive Sciences Indian Institute of Liver and Digestive Sciences Campus, Sitala East, Sonarpur, Kolkata –700150	Human Research Ethics Committee, IILDSSitala East, Sonarpur, Kolkata –700150 ECR/1568/Inst/WB/2021	Dr. Abhijit Chowdhury
3.	Govind Ballabh Pant Institute of Postgraduate Medical Education and Research Delhi, Delhi gate, India, 110002	Institutional Ethics Committee, Maulana Azad Medical College 2, Bahadur Shah Zafar Marg, near Delhi Gate, Balmiki Basti, New Delhi, Delhi, 110002 ECR/329/Inst/DL/2013/RR-19	Dr. Siddharth Srivastava
4.	King George's Medical University Chowk, Lucknow, Uttar Pradesh 226003	Institutional Ethics Committee, King George's Medical University Shahmina Road, Chowk, Lucknow, Uttar Pradesh	Dr. Ajay Kumar

		-226003 ECR/262/Inst/UP/2013/RR-19	
5.	S.R. Kalla Memorial Gastro & 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 ECR/8/Inst/Raj/2013/RR-24	Dr. Mukesh Kalla
6.	Samvedna Hospital B 27/88 G, New Colony, Ravindrapuri, Varanasi, Uttar Pradesh, India 221005	Samvedna Hospital Ethics Committee Samvedna Hospital, B22/88G, New Ravindra Puri Colony, Varanasi ECR/45/Inst/UP/2013/RR-20	Dr. Hemant Kumar Gupta
7.	Deep Hospital, 481, Model Town Road, Pritam Nagar, Model Town, Ludhiana, Punjab, India, 141002	Institutional Ethics Committee, Deep Hospital, 481, Model Town Road, Pritam Nagar, Model Town, Ludhiana, Punjab, India, 141002 ECR/525/INST/PB/2014/RR-20	Dr. Nitin Shanker Behl
8.	AIIMS Hospital, Ansari Nagar, New Delhi, 110029, India	The Institution Ethics Committee All India Institute of Medical Sciences. Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi, 110029, India ECR/538/Inst/DL/2014/RR-20	Dr. Shalimar
9.	IPGME & R, SSKM HOSPITAL, 244, A.J.C. Bose Road, Kolkata - 700020	Research Oversight Committee Institute of Postgraduate Medical Education & Research, 244 Acharya J. C. Bose Road, Kolkata, ECR/35/Inst/WB/2013/RR-24	Dr. Sk. Mahiuddin Ahammed
10.	Medical College and Hospital, 88 College Street Kolkata	Institutional Ethics Committee for Human Research Medical College, Kolkata, 88, College Street Kolkata-700073 ECR/287/Inst/WB/2013/RR-19	Dr. Saubhik Ghosh

11.	BAPS Pramukh Swami Hospital Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India	BAPS Hospital Institutional Ethics Committee BAPS Pramukh Swami Hospital BAPS Pramukh Swami Hospital Adajan Cross Road, Adajan Surat Gujarat - 395009 India ECR/639/Inst/GJ/2014/RR-20	Dr. Parshottam Koradia
12.	Government Medical College, Trivandrum, Kerala -695011	Human Ethics Committee, Medical college, Trivandrum, 695011 ECR/370/Inst/KER/2013/RR-20	Dr Krishnadas Devadas
13.	Apollo Speciality Hospitals Lake view Road, K.K Nagar, Madurai, Tamil Nadu, India	Institutional Ethics Committee- Clinical Studies Lake view Road, K.K Nagar, Madurai, Tamil Nadu, India EC/Inst/43/TN/2013/RR-19	Dr. Madhusudhana n. J
14.	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
15.	Yashoda Hospital, behind Hari Hara Kala Bhavan, Alexander Road, Kummari Guda, Shivaji Nagar, Secunderabad, Telangana-500003	Institutional Ethics Committee for Yashoda Group of Hospitals Yashoda Hospital, Behind Hari Hara Kalabhavan, SP Road, Secunderabad, Telangana-500003 ECR/49/Inst/AP/2013/RR-22.	Dr. Dharmesh Kapoor
16.	IMS, Banaras Hindu University Department of Gastroenterology, Institute of Medical Sciences, Banaras Hindu University, Aurobindo Colony, Bhelpur, Varanasi-22 1005 India	Institutional Ethics Committee, IMS Banaras Hindu University Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar. Pradesh -221005 ECR/526/Inst/UP/2014/RR-20	Dr. Dawesh Prakash Yadav
17.	All India Institute of Medical Sciences Shivaji Nagar, Virbhdra Road, AIIMS Rishikesh, Uttarakhand - 249203	Institutional Ethics Committee Shivaji Nagar, Virbhdra Road, AIIMS Rishikesh, Uttarakhand - 249203 ECR/736/Inst/UK/2015/RR-21	Dr. Rohit Gupta

18.	Sterling Hospital, Opp INOX Cinema , Racecourse , Near Natubhai circle, Vadodara, Gujarat, India	Sterling Ethics Committee Sterling Hospital, Opp. Inox, Race Course Circle, Vadodara, Gujarat -390007 ECR/582/Inst/GJ/2014/RR-20	Dr. Pankaj Jain
19.	Gastroplus Digestive Disease Centre, D-Block,3rd Floor, Galaxy Bazaar, Sunrise park road Vastrapur, Ahmedabad-380054	Gastroplus Ethics committeeD-Block, 3rd Floor, Galaxy Bazaar, Sunrise park road Vastrapur,Ahmedabad-380054 ECR/1207/Inst/GJ/2019-RR-22	Dr. Ravindra Gaadhe
20.	Seven Star Hospital,324, 1, Great Nag Rd, near Jagnade Square, Nandanvan, Nagpur, Maharashtra, India	Ethics Committee Rahate Surgical Hospital conference room 4 th floor, near telephone exchange square, 517-Juni Mangalwari, Centre avenue, Nagpur ECR/601/Inst/MH/2014/RR-20	Dr Prashant Rahate
21.	Lifeline Medicare Hospitals Ground Floor, DLH Park, S.V. Road, near MTNL Signal, Sunder Nagar, Sunder Nagar, Goregaon West.	IEC of New Health Care Nursing Home C Satellite Park Near G.C.C Club Mira Road (E)Thane, Maharashtra -401107 India ECR/1388/Inst/MH/2020	Dr. Sheth Keyur Ashok
22.	Alfa Gastro and Liver care, 207, 208, second floor, dream square complex, near nirnaynagar underbridge, opposite Ramdevpeer ji maharaj mandir, Akhbarnagar Ahmedabad, 380013	Sangini Hospital Ethics Committee Sangini Hospital, 2nd Floor, Sangini Complex, Near Doctor House, Parimal Crossing, Ahmedabad -380006 ECR/147/Inst/GJ/2013/RR-24	Dr. Vatsal Mehta
23.	Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Old Thane-Belapur road, Kalwa, Thane-400605	Institutional Clinical Ethics Committee RGMC and Chatrapati Shivaji Maharaj Hospital. Thane-Belapur Rd, Kalwa, Thane-400605 ECR/469/Inst/MH/2013/RR-20	Dr. Yogesh Sharma
24.	International Gastro Institute, 7th floor, Ishavasyam Multispecialty Hospital LLP, Near Genda Circle, Atlantis Ln, Vadodara-390007, Gujarat, India	Ethics Committee, A Unit of Ishavasyam Multispecialty hospital LLP,Behind Atlantis, Opp. Vadodara Central, Sarabhai Campus, Sarabhai Main Road, Subhanpura, Vadodara 390007, Gujarat, India	Dr. Ashish Sethi

		ECR/1120/Inst/GJ/2018/RR-21	
25.	Institute of Liver & Biliary Sciences D-1, Vasant Kunj, New Delhi-110070	Institutional Ethics Committee, Institute of Liver & Biliary Sciences (ILBS) D-1, Vasant Kumj, New Delhi, South Delhi, Delhi -110070 ECR/67/Inst/DL/2013/RR-24	Dr. Shivkumar Sarin
26.	Dr. Anjan Jyoti Talukdar Department of Medicine, Guwahati Medical College, Narakasur Hilltop, Bhangagarh	Institutional Ethics Committee GMCH Guwahati Medical College and Hospital, 2nd Floor, Guwahati Medical College Main Building, Narakasur Hill Top, Guwahati, Kamrup Metropolitan, Assam -781032 ECR/1470/INST/AS/2020	Dr. Anjan Jyoti Talukdar
27.	Postgraduate Institute of Medical Education and Research, PGIMER, Sector 12 Chandigarh 160012	Institutional Ethics Committee PGIMER Sector 12 Chandigarh 160012 ECR/25/Inst/CH/2013/RR-20	Dr. Jayanta Samanta
28.	Digestive Diseases Centre2, Ankit Puram, GMS Road, Dehradun, Uttarakhand 248001	Institutional Ethics Committee, Digestive Diseases Centre, 2, Ankit Puram, GMS Road, Dehradun, Uttarakhand 248001 ECR/1671/Inst/UK/2022	Dr Sanjay Gupta
29.	Belagavi Institute Of Medical Sciences Belagavi Dr B R Ambedkar Road, Belagavi 590001	Institutional Ethics Committee (IEC) BIMS Institutional Ethics Committee BIMS Belagavi Institute Of Medical Sciences, Belagavi Dr B R Ambedkar Road Belgaum Belagavi (Belgaum) Karnataka -590001 India ECR/801/Inst/KA/2016/RR-20	Dr Shrishail Hanagandi

30.	PT B D Sharma PGIMS Rohtak, Haryana, Medical Rd, Rohtak, Haryana 124001	IEC PGIMS Rohtak, Haryana 124001 ECR/293/Inst/HR/2013/RR-19	Dr. Sandeep Goyal
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