Tele No.011-23236965
Fax.No.011-23236973

F. No. ND/MA/24/000162
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-11 0002

To
M/s Mankind Pharma Ltd. 208,
Okhla Industrial Estate, Phase-III
Delhi (India) – 110020

Subject: Application for grant of permission to conduct Phase-III Clinical Trial of Resmetirom Tablets 60mg, 80mg & 100mg titled- "A prospective, multicentric, double-blind, double-dummy, placebo controlled, Parallel-group, Phase-3 clinical study to evaluate the efficacy, safety of Resmetirom Tablets (strengths 60 mg, 80 mg and 100 mg) in subjects with Non-cirrhotic, Non-alcoholic Steatohepatitis (NASH) with moderate to Advanced Liver Fibrosis (Consistent with Stages F2 to F3 Fibrosis)" Protocol no. ECTS/25/004 Version no. 01, Date: 19-May-2025-regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2024/46478 dated 22.11.2024**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/14/2025** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.07.01 16:34:03 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Conditions of permission

(i) 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;

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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 of the New Drugs and Clinical Trials Rules, 2019;

(xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules 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;

(xii) 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 the 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;

(xiii) 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 authorized 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;

(xiv) 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;

(xv) The Laboratory owned by any person or a company or any other legal entity and utilized 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;

(xvi) 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;

(xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) The Informed Consent Document including ICF and Patient Information Sheet should clearly mention in understandable language about the details of the drug therapy that the patient may or may not receive.

(xx) The firm should include sites preferably having liver disease management facility.

FORM CT-06

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

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

CT Permission No. CT/ND/14/2025

The Central Licensing Authority hereby permits **M/s Mankind Pharma Ltd. 208, Okhla Industrial Estate, Phase-III, Delhi (India) - 110020 Telephone: 011-46541111, 47476600 Fax: 011-46541382, 47476666 E-Mail: ISHA.RAWAT@MANKINDPHARMA.COM** to conduct clinical trial of the new drug as per **Protocol no. ECTS/25/004 Version no. 01, Date: 19-May-2025** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

Names of the new drug ~~or investigational new drug:~~	**Resmetirom Tablets 60 mg, 80 mg, 100 mg**
Therapeutic class:	Thyroid hormone receptor beta agonist
Dosage form:	Tablets
Composition:	Each tablet contains Resmetirom Tablets……. 60/80/100 mg
Indications:	Resmetirom Tablets is indicated in conjunction with diet and exercise for the treatment of adults with Non-Cirrhotic Non-Alcoholic Steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	**Dr Vinay Kumar (Professor)** Post Graduate Department of Medicine, GSVM Medical College, Kanpur-208002, UP, India	Ethics Committee GSVM Medical College, GSVM Medical College, Kanpur-208002, UP, India **ECR/680/Inst/UP/2014/RR-20**
2	**Dr Rajesh Pendlimari** Rajlakshmi Hospital & Research Center, Room no. -2, 21/1, Lakshmipura Main Road, Vidyaranapura Post, Bangalore-560097	Rajlakshmi Hospital Institutional Ethics Committee 21/1, Lakshmipura Main Road, Vidyaranapura Post, Bangalore-560097 **ECR/809/Inst/KA/2017/RR-20**
3	**Dr Make Naveen Chand** Department of Gastroenterology, Visakha Institute of Medical Sciences Hanumanthavaka, Visakhapatnam-530040, Andhra Pradesh	Visakha Institute of Medical Sciences S.No. 97/2, Chinnagadilli Village, Hanumanthavaka, Visakhapatnam-530040, Andhra Pradesh **ECR/1421/Inst/AP/2020**

4	**Dr Shachish Piyush** Alfa Gastro and Liver Care, 605, 6th floor, Aagam Avenue, Nr. Adani CNG Pump, Sabarmati, Ahmedabad-380005	Riddhi Medical Nursing Home IEC, Riddhi Medical Nursing Home., A/101, Jalaram Plaza, Jawahar Chowk, Maninagar, Ahmedabad, Gujarat-380008, India **ECR/886/Inst/GJ/2016/RR-24**
5	**Dr. Vipul Kumar Bachubhai Prajapati (MD General Medicine)** Department of Medicine, GCS medical College, Hospital & Research Center, opp. DRM office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad-380025, Gujarat, India	Institutional Ethics Committee, GCS medical College, Hospital & Research Center, opp. DRM office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad-380025, Gujarat, India **ECR/339/Inst/GJ/2013/RR-24**
6	**Dr Pinaki Roy** Assistant Professor, Department of Gastroenterology Nil Ratan Sircar medical College & Hospital, 138, Acharya Jagadish Chandra Bose Road, Kolkata-700014, West Bengal, India	Institutional Ethical Committee, NRS Medical College, Nil Ratan Sircar Medical College and Hospital, 18, Acharya Jagadish Chandra Bose Road, Kolkata-700014, West Bengal **ECR/609/Inst/WB/2014/RR-20**
7	**Dr. Dharmendra BL Associate Professor** Department of Gastroenterology K R hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001	IEC-MMC and RI and ssociated Hospital, Mysore Medical College and Research Institute, Mysore-570001 **ECR/134/Inst/KA/2013/RR-19**
8	**Dr Kamlesh Magnani** Nand Hospital, Nr. Panchmukhi Hanuman Mandir, Vasna-Bhayli Road, Vadodara, Gujarat-390015	Anand Institutional Ethics Committee, B Tower, Sundervan Complex, Gorwa Refinery Rd. near Gorwa, Beside IOCL Petrol Pump, Gorwa, Vadodara-390016 **ECR/725/Inst/GJ/2015/RR-21**
9	**Dr Krunal Patel, Consultant Gastroenterologist** Jivan Gastro and Gynaec Hospital, Block-C Ground Floor, SP Square, Beside Croma Center, New Maninagar, Vastral Road, Ahmedabad-382449, Gujarat, India	Riddhi Medical Nursing Home IEC, Riddhi Medical Nursing Home., A/101, Jalaram Plaza, Jawahar Chowk, Maninagar, Ahmedabad, Gujarat-380008, India **ECR/886/Inst/GJ/2016/RR-24**
10	**Dr. Saubhik Ghosh, Associate Professor,** Department of Gastroenterology, 3rd Floor, MCH Building, Medical College and Hospital, 88, College Street, Kolkata-70073, 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**
11	**Dr. Manoj Kumar Assistant Professor,** Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India	Institutional Ethics Committee Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan-305001, India **ECR/1156/Inst/RJ/2018/RR-22**

12	**Dr. Shailesh Dube** Mahavir Hospital, Mahavir Status, Nr. K P height, Nr Manmohan Cross Road, New Nikol, Ahmedabad-382350	Mahavir Hospital Ethics Committee, 1st Floor, Mahavir Status, Nr. K P height, Nr Manmohan Cross Road, New Nikol, Ahmedabad-382350 **ECR/1786/Inst/GJ/2023**
13	**Dr. Shyam Sunder Sharma (HoD, Department of Gastroenterology)** Manglam Plus Medicity Hospital, Shipra Path, Sector-5, Mansarovar, Jaipur-302020, Rajasthan	IEC - Manglam Medicity Hospital, Manglam Plus Medicity Hospital, Shipra Path, Sector-5, Mansarovar, Jaipur-302020, Rajasthan **ECR/1643/Inst/RJ/2022**
14	**Dr. Keyur Brahme (Assistant Professor, Department of Medicine,** Government Medical College and Sir Sayajirao Government Hospital (SSGH), Gujarat-India, OPD-18, First Floor, Department of Medicine, Jail Road, Indira avenue, Sayajiganj, Vadodara-390001, Gujarat	Institutional Ethics Committee for Human Research (IECHR) Medical College, Baroda, Room Number 2, First Floor, Department of Pharmacology, Medical College Baroda, Anandpura, Vadodara -390001, Gujarat, India. **ECR\85\Inst\GJ\2013\RR-24**
15	**Dr. Ankit Makadia** Gokul Hospital, 12/14 Malhar Plot, Near, Virani Chowk, Vidhyanagar Main Road, Rajkot-360002, Gujarat-India	Institutional Ethics Committee Gokul Lifecare Private Limited, 12/14 Malhar Plot, Near, Virani Chowk, Vidhyanagar Main Road, Rajkot-360002, Gujarat-India **ECR/1469/Inst/GJ/2020**
16	**Dr. Vatsal Mehta** OHM Hospital, 41/A, Karmacharinagar-1, Opp. Alkapuri Society, Bhuyangdev-Ghatlodia Road, Ghatlodia, Ahmedabad-380061	OHM Hospital Ethics Committee, 41/A, Karmacharinagar-1, Opp. Alkapuri Society, Bhuyangdev-Ghatlodia Road, Ghatlodia, Ahmedabad-380061 **ECR/1917/Inst/GJ/2024**

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.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi