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F. No. ND/MA/21/000050
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 18 MAY 2021

To
M/s Hetero Labs Limited,
7-2-A2, Industrial Estates, Sanathnagar,
Telangana, India-5000018.

Subject:- Permission for conducting clinical study entitled, "A Phase III, Multicentric, Prospective, Randomized, Parallel Study to Evaluate the Efficacy and Safety of Molnupiravir in Adult Indian Patients with Moderate COVID-19" Amended Protocol HCR/III/MOLCOV/04/2021-02, Version Number 3.0, dated 07.05.2021- regarding.

Sir,

With reference to your Application No. ND/MA/21/000050 dated 30.05.2021, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/ 52 /2021** to conduct the subject mentioned clinical trial under the provisions of **New Drugs and Clinical Trial Rules, 2019** granted based on evaluation in consultation with Subject Expert Committee (SEC) as part of accelerated approval process in light of COVID 19 outbreak.

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

Yours faithfully

(Dr. V. G. Somani)
Central Licensing Authority
Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Condition 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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority;

(ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of

receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 Licensing 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 Licensing 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 study should be conducted in two parts and termed as Phase II/III Clinical trial.**

(xx) **In part I, the study should be conducted in 100 patients and submit interim Clinical trial data to CDSCO for further consideration.**

(xxi) **RTPCR test should be done at 5, 10 and 15 days of the study.**

(xxii) **Sample size should be atleast 1218 mild COVID patients in randomized 1:1 ratio into Test: Reference arm.**

(xxiii) **Patients aged limit should be 18 to 60 years.**

FORM CT-06

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

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

The Central Licensing Authority hereby **M/s Hetero Labs Limited, 7-2-A2, Industrial Estates, Sanathnagar, Telangana,India-5000018** to conduct clinical trial of the investigational new drug as per **HCR/III/MOLCOV/04/2021-01, Version Number 3.0, dated 07.05.2021** 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:	**Molnupiravir Capsules 200mg**
Therapeutic class:	**Antiviral**
Dosage form:	**Capsules**
Composition:	**Each capsule contains.....Molnupiravir 200mg**
Indications:	**Molnupiravir is indicated for the treatment of mild to moderate COVID-19 infection**

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
01	Dr K. Sunil Naik, MD (General Medicine) Associate Professor, Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam– 532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College & Govt. General Hospital, Srikakulam - 532001 Andhra Pradesh, India ECR/492/Inst/AP/2013/RR-20
02	Dr. S. K. Noushad Ali MD(General Medicine) Assistant Professor, ACSR Government Medical College & Hospital, Dargamitta, Nellore-524004, Andhra Pradesh	Institutional Ethics Committee, ACSR Government Medical College & Hospital, Dargamitta,Nellore-524004 ECR/961/Inst/AP/2017/RR-20
03	Dr. Keyur Bramhe MD (Internal Medicine) Assistant Professor, Shree sir Sayaji General Hospital, Jail Road, Indira Avenue, Vadodara, Gujarat	Institutional Ethics Committee for Human Research, Jail Road, Indira Avenue, Vadodara, Gujarat 390001 ECR/85/Inst/GJ/2013/RR-19

04	Dr. Chirag Rathod MD (General Medicine) Associate Professor, GMERS Medical College &Hospital, Gotri, Vadodara-390021,Gujarat	Institutional Human Ethics Committee,1st Floor College Building, GMERS Medical College & Hospital,Gotri,Vadodara -390021,Gujarat, India ECR/28/Inst/GJ/2013/RR-19
05	Dr. Veer Bahadur Singh MD(General Medicine) Principal &Controller, Jawahar Lal Nehru Medical College, Kala Bagh,Ajmer-305001,Rajasthan	Institutional Ethics Committee Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan ECR/1156/Inst/RJ/2018
06	Dr. Venkateshwara Rao DNB (General Medicine) Consultant Internal Medicine, St. Theresa's Hospital Sanathnagar, Hyderabad-500018, Telangana	Ethics Committee, St. Theresa's Hospital Sanathnagar. Hyderabad -500018, Telangana state, India ECR/230/Inst/AP/2013/RR-19
07	Dr. Swapnav Borthakur, MD (General Medcine) Consultant physician, Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam	Ethics Committee Down Town Hospital, Dispur, G.S.Road, Guwahati-781006 ECR/549/Inst/AS/2014-RR-20
08	Dr. Deo Nidhi Mishra MD (Internal Medicine) Senior Consultant Physician, Nirmal Hospital, Opp.MLB Medical college, Gate no 3, Jhansi -284128, Uttar Pradesh	Institutional Ethics Committee, Nirmal Hospital Institutional Ethics Committee, Nirmal Hospital, Jhansi Opp Gate no 3, MLB Medical college, Jhansi (U.P),284128-India ECR/325/Inst/UP/2013/RR-19
09	Dr S. Vasanth Kumar, Assistant Professor, MBBS,MD(General Medicine), Gandhi Hospital, Department of Medicine, In Patient Block,3rd Floor, Musheerabad, Secunderabad, Telangana, India-500003	Institutional Ethics Committee ,Gandhi Medical College/ Hospital, Musheerabad, Secunderabad,Telangana-500003 ECR/180/Inst/AP/2013/RR-19
10	Dr. Koushik Basu, MBBS,MD(General Medicine), Assistant Professor, MCH Building 4th floor, department of General Medicine, Medical college and hospital,88 college street,Kolkata-700073,west Bengal	Institute ethics committee for humar research medical college and hospital, 88 college street,Kolkata-700073,west Bengal ECR/287/INST/WB/2013/RR-19
11	Dr. Atul Jindal, MBBS, MD (Pediatric) DM (Pediatric) Associate Professor, Department of General Medicine, All India Institute of	Institutional Ethics Committee AIIMS Raipur Room no.-2103,2nd floor, Medical college Complex,

	Medical Science, Great Eastern Road. Tetibandh, Raipur, 492099, Chhattisgarh, India	Gate no-5,AIIMS, Raipur, 492099, Chhattisgarh ,India ECR/714/Inst/CT/2015/RR-21
12	Dr. Aravind Kumar Kankane, MBBS MD (Internal Medicine) DM (Neurology), Associate Prof. Neurology, MLB Medical College ,Jhansi(U.P)-284128	Ethics committee,MLB Medical college MLB Medical college& Associated Hospital, MLB Medical college Kanpur Road ,Jhansi UP 284128 ECR/1393/Inst/UP/2020
13	Dr. Sawardekar Vinayak Maruti MBBS, MD (Medicine) Associate Professor, Department of Medicine ,St George'S Hospital PD Mello Road, Fort, Mumbai-400001	Institutional Ethics Committee GGMC, Mumbai Grant Govt Medical College J.J Road J.J Hospital Compound Mumbai - 400008 Maharashtra ECR/382/Inst/MH/2013/RR-19
14	Dr. K. Prasanna Purna MBBS,MD(Pulmonolgy) Professor & Head, Deaprment of Respiratory Medicine Narayana Medical College and Hospital Nellore-524003 Andhra pradesh,India	Ethics Committee Narayana Medical College and Hospital, Chinthareddypalem,Nellore-524003,Andhra Pradesh ECR/46/Inst/AP/2013/RR-19
15	Dr. Rajendra Dhar, MBBS, MD(Pulmonologist) Professor, National Institute of Medical Sciences and Research(NIMS) Shobha Nagar, Jaipur-Delhi Highway NH-11C Jaipur-303121	Institutional Ethics Committee National Institute of Medical Sciences and Research(NIMS) Shobha Nagar, Jaipur-Delhi Highway NH-11C Jaipur-303121 ECR/665/Inst/RJ/2014/RR-17

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.

(Dr. V. G. Somani)
Central Licensing Authority
Stamp
Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

New Delhi
Date: 18.MAY.2021

CT/ND/31 /2021