

F. No. ND/MA/21/000044

Government of India

Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

Tele No.011-23236965

Fax.No.011-23236973

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

11 8 MAY 2021

To

M/s Optimus Pharma Private Limited,
Sy. No. 37/A & 37/P, Plot no. 6P,
2nd Floor, Signature Towers, Kothaguda,
Kondapur, Hyderabad,
Telangana (India) – 500084.

Subject:- Permission for conducting clinical study entitled, "A prospective, randomized, parallel, multicentric, Phase II/III clinical trial to assess the efficacy and safety of Molnupiravir 800 mg capsules and standard of care (SOC) compared to standard of care (SOC) only in patients with polymerase chain reaction (RT-PCR) confirmed moderate COVID-19 infection" Protocol No: OPT-MOL-002, Version Number 1.0, dated 12.05.2021- regarding.

Sir,

With reference to your Application No. **ND/CT21/BO/2021/25231** dated **24.04.2021**, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/46/2021** 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

Condition of permission

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
Bhawan Kotla Road, New Delhi-110002

- (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 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;
- (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 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;
- (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 study should be conducted in two parts and termed as Phase II/III Clinical trial.**

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

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

c) Sample size should be atleast 1282 moderate COVID patients in randomized 1:1 ratio into Test: Reference arm.

Test Arm

Molnupiravir 800 mg (4 capsules of 200 mg) administered orally every 12 hours for 5 days (10 doses total) plus Standard of Care.

Reference Arm

Standard of Care

d) Patients age 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 permits **M/s Optimus Pharma Private Limited, Sy. No. 37/A & 37/P, Plot no. 6P, 2nd Floor, Signature Towers, Kothaguda, Kondapur, Hyderabad, Telangana (India) – 500084, Telephone No: 91-8455-223653** to conduct clinical trial of the investigational new drug as per protocol number **OPT-MOL-002, Version Number 1.0, dated 12.05.2021** 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:		For the treatment of non hospitalised patients with moderate COVID-19
Details of clinical trial sites-		
Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
01	Dr. Pawan Kumar Singh Pt B.D.S PGIMS, Medical Rd, Rohtak, Haryana 124001	Institutional Ethics Committee PGIMS UHS Rohtak ECR/293/Inst/HR/2013/RR-19
02	Dr Neha Singh AIIMS Patna Aurangabad Rd, Phulwari Sharif, Patna, Bihar 801507	IEC-AIIMS-P All India Institute of Medical Sciences, Patna Phulwarisharif Patna Bihar ECR/1387/Inst/BR/2020
03	Dr Nalini Kadgi B.J. Government Medical College, Jai Prakash Narayan Road, Railway Station Rd, Pune, Maharashtra 411001	Ethics Committee B J Medical College and SGH ECR/433/Inst/MH/2013/RR-19
04	Dr K J Upadhyay B.J. Medical College and Civil hospital, Asarwa, Ahmedabad, Gujarat, 380016	Institutional Ethics Committee, B.J. Medical College & Civil Hospital, Ahmedabad-380 016 ECR/72/Inst/GJ/2013/RR-19
05	Dr Saurabh Srivastava	

	Government Institute of Medical Sciences Greater Noida, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh 201310	GIMS Institutional Ethics Committee situated at Government Institute of Medical Sciences Kasna Greater Noida Gautam Buddha Nagar Gautam Buddha Nagar Uttar Pradesh ECR/1224/Inst/UP/2019
06	Dr Sushant Meshram Government Medical College Nagpur Hanuman Nagar, Ajni Rd, Medical Chowk, Ajni, Nagpur, Maharashtra 440003	Institutional Ethics Committee, GMC Nagpur situated at Government Medical College and Hospital Nagpur Government Medical College Medical Square Hanuman Nagar Nagpur, Maharashtra ECR/43/Inst/MH/2013/RR-19
07	Dr Ram Kalgud Karnataka Institute of Medical Sciences Hubli, PB Rd, Vidya Nagar, Hubli, Dharwad, Karnataka 580022	KIMS Ethics Committee Karnataka Institute of Medical Sciences Office of the Principal Vidyanagar HUBBALLI Dharwad Karnataka ECR/486/Inst/KA/2013/RR-20
08	Dr K Narasmhulu Kurnool Medical College, Near Bhudawarapet Bharath Petroleum, Kisan Ghat Rd, Kurnool, Andhra Pradesh 518002	Institutional Ethics Committee Kurnool Medical College/Government General Hospital Budhawarpet, Kurnool Andhra Pradesh ECR/1397/Inst/AP/2020
09	Dr M Natrajan Madurai Medical College, Collector Office Road Near, Alwarpuram, Madurai, Tamil Nadu 625020	Institutional Ethics Committee Madurai Medical College and Govt. Rajaji Hospital Madurai Medical College Panagal Road Madurai Madurai Tamil Nadu - 625020 India ECR/1365/Inst/TN/2020
10	Dr Ram Manohar Jaiswal Mahatma Gandhi Medical College and Hospital Jaipur, Tonk Rd, near India International School, Ricco Industrial Area, Sitapura, Jaipur, Rajasthan 302022	Institutional Ethics Committee Mahatma Gandhi Medical College and Hospital Jaipur, Tonk Rd, near India International School, Ricco Industrial Area, Sitapura, Jaipur, Rajasthan 302022 ECR/125/Inst/RJ/2013/RR-16
11	Dr Millind Baldi Mahatma Gandhi Memorial Medical College Indore AB Rd, CRP Line, Indore, Madhya Pradesh 452001	Ethics Committee Mahatma Gandhi Memorial Medical College & Maharaja Yashwantrao Hospital, Indore Room No.413 4 th floor MY Hospital

		Indore-452001
		ECR/397/Inst/MP/2013/RR-16
12	Dr J Inbanthan Mysore Medical College, Mysuru, Karnataka India 570021	Mysore Medical College & Research Institute and Associated Hospitals Department of Pathology K.R Hospital Irwin Road Mysore 570021
		ECR/134/Inst/KA/2013/RR-16

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.

V. G. Somani

(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: ...1...8...MAY 2021

