

F. No. IND/CT/21/000023
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:

19 MAY 2021

To

M/s Strides Pharma Science Limited
Strides House, Bilekahalli,
Bannerghatta Road, Bengaluru
Karnataka (India) – 560076.

Subject:- Permission for conducting clinical study entitled, "A Multi-Centre, Prospective, Open Label, Parallel, Randomized, Clinical Trial to Assess the Efficacy and Safety of Molnupiravir 800 Mg Capsules and Standard of Care Compared to Standard of Care Only in Moderate Patients with Polymerase Chain Reaction (PCR) Confirmed COVID-19" Protocol No. NV-05-1155-2021, Version Number 1.0, dated 14.05.2021- regarding.

Sir,

With reference to your Application No. **IND/CT04/FF/2021/25536** dated **06.05.2021**, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/ /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

- (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) Undertaking by Investigators along with all supportive documents as per New Drugs and Clinical Trials Rules, 2019 shall be submitted before initiation of clinical trial.
- (xx) **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 Strides Pharma Science Limited, Strides House, Bilekahalli, Bannerghatta Road, Bengaluru, Karnataka (India) – 560076, Telephone No: 9845106772, FAX: 8067840700** to conduct clinical trial of the investigational new drug as per protocol number - **NV-05-1155-2021, Version Number 1.0 dated 14.05.2021** 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 400mg	
Therapeutic class:	Antiviral	
Dosage form:	Capsules	
Composition:	Each capsule contains.....Molnupiravir 400mg	
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 Meenakshi Bhattacharya Government Medical College, University Rd, Jubilee Park, Aurangabad, Maharashtra 431004	Institutional Ethics Committee Government Medical College Aurangabad Ethics committee, Department of Pharmacology, Maharashtra - 431001 India ECR/314/Inst/MH/2013/RR-19
02	Dr Atul Rajkondawar Government Medical College and Hospital, Hanuman Nagar, Ajni Rd, Medical Chowk, Ajni, Nagpur, Maharashtra 440003	Institutional Ethics Committee, Government Medical College and Hospital, Nagpur, Medical Square Hanuman Nagar, Nagpur Maharashtra - 440003 India ECR/43/Inst/MH/2013/RR-19
03	Dr Yogesh Sharma Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital, 1, Thane - Belapur Rd, Kalwa West, Budhaji Nagar, Kalwa, Thane, Maharashtra 400605	Institutional Clinical Ethics Committee RGMC and Chatrapati Shivaji Maharaj Hospital. Thane-Belapur Rd, Kalwa, Thane- 400605 Maharashtra, India ECR/469/Inst/MH/2013/RR-20

04	Dr Talukdar Biplabendu Government of West Bengal Medical College & Hospital, Kolkata 88, College Street, Kolkata- 700073	Institutional Ethics Committee for Human Research, Medical College , Kolkata 88, College Street Kolkata, Kolkata West Bengal - 700073 India ECR/287/Inst/wB/2013/RR-19
05	Dr Jigar Modia Jupiter Hospital, 9, Suryavilas society, Near Gotri Police station, Gotri, Vadodara 390021	Anand Institutional Ethics Committee Anand Multispecialty Hospital, Vadodara B Tower Sundarvan Complex, Beside IOCL Petrol Pump Near Gorwa ITI Vadodara Vadodara Gujarat - 390016 India ECR/725/Inst/GJ/2015/RR-21
06	Dr. Karishma Manwani Gujarat Kidney and Super speciality Hospital, Vadodara, New India Mill Compound, Nr. Jetalpur Road, Jetalpur Bridge, Anand Nagar, Haripura, Vadodara, Gujarat 390020	Anand Institutional Ethics Committee Anand Multispecialty Hospital, Vadodara B Tower Sundarvan Complex, Beside IOCL Petrol Pump Near Gorwa ITI Vadodara Vadodara Gujarat - 390016 India ECR/725/Inst/GJ/2015/RR-21
07	Dr Balachandra G BGS Global Institute of Medical Sciences, Dr.Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka 560060	Institutional Ethics Committee Department of Community Medicine, Room no: 01, Second floor, College Building BGS Global Institute of Medical Sciences 67 BGS Health and Education City Uttarahalli Road, Kengeri Bangalore South Karnataka Bengaluru ECR/1307/Inst/KA/2019
08	Dr.K.Sunil Naik Govt. Medical College & Govt. General Hospital (Old RIMSGGH), Hudco Colony, Balaga, Srikakulam, Andhra Pradesh 532001	Institutional Ethics Committee Govt. Medical College Govt.General Hospital Balaga Srikakulam Andhra Pradesh - 532001 India ECR/492/INST/492/2013/RR-20
09	Dr. Aman Khanna Aman Hospital and Research Center , 15, Shashwat, Opp. E.S.I Hospital, Gotri Road, Vadodara	An Institutional Ethics Committee Aman Hospital and Research Centre 15 Shashwat, Opp, E.S.I Hospital Sarabhai, Gotri Road Vadodara Gujarat - 390021 India ECR/857/Inst/GJ/2016/RR-19

10	Dr. Anand Patel Anand Multispeciality Hospital, B-Tower sundervan complex, Gorwa Refinery Rd, near Gorwa, beside IOCL Petrol pump, Gorwa, Vadodara, Gujarat 390016	Anand Institutional Ethics Committee Anand Multispecialty Hospital, Vadodara B Tower Sundarvan Complex, Beside IOCL Petrol Pump Near Gorwa ITI Vadodara Vadodara Gujarat - 390016 India ECR/725/Inst/GJ/2015/RR-21
----	---	--

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

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

New Delhi

Date:

19 MAY 2021

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