



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION(Headquarter)(Directorate General of Health Services) Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.:91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/22/000172

To

M/s IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103
Mob: + 91 9958881837 Email: Sneha.gupta2@iqvia.com

Sir,

With reference to your application no. GCT/CT04/FF/2022/35226 (GCT/172/22) dated 16-12-2022, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3 clinical trial titled, “ **A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19**” Protocol no. AT-03A-017, Version 1.0, Final dated 08/Sep/2022 with a total of up-to 200 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) 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 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 electronically in the SUGAM portal;
- (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;
- (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 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;
- (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 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 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.

Digitally signed by RAJEEV SINGH RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
DN: cn=RAJEEV SINGH RAGHUVANSHI,
o=RAJEEV SINGH RAGHUVANSHI,
ou=RAJEEV SINGH RAGHUVANSHI,
email=rajeev.singh@rajeevsinghraghuvanshi.com,
c=IN, postalCode=041015306554fe67754b765db1cb,
serialNumber=657F5E47D940985D0F38DC902D0E
1FE73F412A1A126EA94FA5701124A19013,
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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. IQVIA RDS (India) Private Limited, Omega Embassy TechSquare Marathahalli - Sarjapur Outer Ring Road, Kadubeesanahalli, Bangalore – 560103, Karnataka Mob.: + 91 9958881837 Email: Sneha.gupta2@iqvia.com** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. AT-03A-017, Version 1.0, Final dated 08/Sep/2022** 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 _____

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 DN: cn=RAJEEV SINGH RAGHUVANSHI, o=RAJEEV SINGH RAGHUVANSHI,
 ou=RAJEEV SINGH RAGHUVANSHI, postalCode=600034, st=TAMIL NADU,
 serialNumber=1, email=rajeev.singh.raghuvanshi@gmail.com,
 1FE73CF812A1120B94F370124A19013,
 cn=RAJEEV SINGH RAGHUVANSHI
 Date: 2023.05.19 11:00:41 +05'30'

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	Bemnifosbuvir Hemisulfate (BEM; AT-527)
Therapeutic class:	Antiviral
Dosage form:	Tablets
Composition:	Silicified Microcrystalline Celluloseb = 37.5000 mg/tablet U.S.P. Inactive Bemnifosbuvir Hemisulfate (AT-527/Bemnifosbuvir = 298.3000 mg/tablet In House Specification Active Microcrystalline Cellulose = 234.1000 mg/tablet U.S.P., J.P., Ph. Eur Inactive Mannitol = 90.0000 mg/tablet U.S.P. Inactive Croscarmellose Sodium =71.3000 mg/tablet U.S.P., J.P., Ph. Eur Inactive Colloidal Silicon Dioxide =7.5000 mg/tablet U.S.P., J.P., Ph. Eur Inactive Magnesium Stearate = 11.3000 mg/tablet U.S.P., J.P., Ph. Eur Inactive
Indications:	COVID-19

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	MAVEN'S Hospital, N 37, Opposite Reliance Fresh, Vaishali Nagar, Ajmer-305001, India	Maven's Institutional Ethics Committee, MAVEN'S Hospital, N 37, Opposite Reliance Fresh, Vaishali Nagar, Ajmer-305001, India ECR/157/Inst/RJ/2013/RR-20	Dr. Jaiprakash Kewlani
2.	ESIC Medical College & Hospital, NH-3, NIT, Faridabad, Haryana, India-121001	Room no 301, 3rd floor, Department of Physiology, Academic Building, Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana, India-121001 ECR/1539/Inst/HR/2021	Dr. Anil Kumar Pandey
3.	Chopda Medicare Research Centre Pvt. Ltd., Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik - 422005, Maharashtra, India	Magna-Care Ethics Committee, Chopda Medicare Research Centre Pvt. Ltd., Magnum Heart Institute, Canada Corner, Nashik -422005, Maharashtra, India ECR/79/Inst/MH/2013/RR-19	Dr. Sakhala Swapnil Suresh
4.	Tagore Hospital & Research Institute, Tagore Lane, Sector-7, Shipra Path, Madhayam Marg, Mansarovar, Jaipur-302020, Rajasthan, India	Tagore Hospital Ethics Committee, Tagore Hospital & Research Institute, Tagore Lane, Sector-7, Shipra Path, Madhayam Marg, Mansarovar, Jaipur-302020, Rajasthan, India ECR/1489/Inst/RJ/2021	Dr. Sandeep Jain
5.	Unity Trauma Centre and ICU (Unity Hospital), Nr. D.R. World, Opp Raghuvir Business Empire, Aai Mata Road, Parvat Patiya, Surat, Gujarat, India	Unity Hospital Ethics Committee Unity Trauma Centre and ICU, N-4 Janki Park Society, Aai Mata Road, Parvat Patiya, Surat, Gujarat-395010 India ECR/1226/Inst/GJ/2019	Dr Maheshkumar Vithalbhai Sutariya
6.	Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway ,Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057,	Dr. Sachin Kisan Shivnitwar

		Maharashtra, India ECR/751/Inst/MH/2015/RR-21	
7.	Clinical Research Room, Department of General Medicine, King George Hospital, Andhra Medical College, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh, India	Institutional Ethics Committee King George Hospital, Maharanipeta, Collector's Office Junction, Visakhapatnam-530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. Yandrapati Gnaana Sundara Raju
8.	VHS Infectious Diseases Medical Centre, CART Clinical Research Site, Voluntary Health Services, Rajiv Gandhi Salai, Taramani, Chennai-600113	Institutional Ethics Committee, The Voluntary Health Services, Multi-Speciality Hospital & Research Centre, Rajiv Gandhi Salai, Adyar, Chennai, Tamil Nadu-600113, India ECR/752/InstTN/2015/RR-22	Dr. Nagalingeswaran Kumarasamy
9.	Siddhi Hospital, P-67, MIDC, Satpur, Behind ITI, Trimbak Road, Nashik-422007, Maharashtra, India	Siddhi Hospital Ethics Committee (SHIEC), C/O Mutha Hospital, P-67, MIDC, Satpur, Behind ITI, Trimbak Road, Nashik-422007, Maharashtra, India ECR/739/Inst/MH/2015/RR-21	Dr. Abhinandan Bhikchand Mutha
10.	DEC HEALTH CARE, OPD Room NO: 04 16/2/219, Pogathota, Nellore, Andhra Pradesh - 524001, India	VIJAYA ETHICS COMMITTEE, Vijaya Super Speciality Hospital, 16-II/41A, Raghava Cine Complex Road, Pogathota, Nellore, Andhra Pradesh - 524001, India ECR/453/Inst/AP/2013/RR-19	Dr. M Manoj Kumar
11.	Vijaya Super Speciality Hospital, OPD Room NO: 07, 16-II/41 A, Raghava Cine Complex Road, Pogathota, Nellore, Andhra Pradesh -524001, India	VIJAYA ETHICS COMMITTEE, Vijaya Super Speciality Hospital, 16-II/41A, Raghava Cine Complex Road, Pogathota, Nellore, Andhra Pradesh - 524001, India ECR/453/Inst/AP/2013/RR-19	Dr. Changalva Premdeep
12.	Shetty's Hospital, Plot No 11&12, 12 th 'F' Main, Kaveri Nagar, Bommanahalli, Bengaluru-560068, Karnataka, India	Shetty's Hospital Ethics Committee, Shetty's Hospital, Plot No 11&12, 12 th 'F' Main, Kaveri Nagar, Bommanahalli, Bengaluru-560068, Karnataka, India ECR/918/Inst/KA/2017/RR-20	Dr. Poorna Prasad S

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13.	BGS Global Institute of Medical Sciences, No. 67, BGS Health & Education City, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India	Institutional Ethics Committee, Department of Community Medicine, Room No. 01, Second Floor, College Building, BGS Global Institute of Medical Sciences, No. 67, BGS Health & Education City, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India ECR/1307/Inst/KA/2019	Dr. Mohan M E
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