File No. CT/40/21-DCG(I)

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

सत्यमेव जयते

File No. CT/21/000042

To,

M/s IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103.

Sir,

With reference to your application No. GCT/CT04/FF/2021/24830 (GCT/40/21) dated 29-04-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **A randomized, double-blind, placebo-controlled, multicenter study of ensovibep (MP0420) in ambulatory adult patients with symptomatic COVID-19", Protocol No.: MP0420-CP302 (CSKO136A12201J) Version No. 01 dated 17-June-2021** 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) Subjects with respiratory rate more than 24/min and SpO2 level less than 94% should be excluded from the study. Accordingly, firm shall submit the revised protocol to CDSCO.
(ii) Trial sites should be geographically distributed across the country.
(iii) The firm shall submit phase II data prior to initiation of phase III part of the study.
(iv) 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;
(v) 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;

(vi) 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;
(vii) 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;
(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) 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;

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

(xxi) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345d8b2d489612379a1471bfdae9f0b2baa0fc83bfdba2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date:

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

File No. CT/40/21-DCG(I)

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 (India) – 560103** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: MP0420-CP302 (CSKO136A12201J) Version No. 01 dated 17-June-2021** 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.

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2021.07.30 15:18:28 +05'30'

Place: New Delhi
Date _____

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing 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	Ensovibep
Therapeutic class:	Inhibit sars cov 2 virus spike protein RBD ACE2
Dosage form:	Solution for infusion
Composition:	Ensovibep/MP0420 =15.0000 mg/ml in House Specification Active
Indications:	Ambulatory adult patients with symptomatic COVID-19

File No. CT/40/21-DCG(I)
Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	St. Theresa's Hospital, Sanathnagar, Hyderabad, 500018, Telangana, India	Ethics Committee, St. Theresa's Hospital, Sanathnagar, Hyderabad, 500018, Telangana, India ECR/230/Inst/AP/2013/RR-19	Dr. A.Venkateshwar Rao
2.	St. George's Hospital, Grant Government Medical College & Sir JJ Group of Hospitals, P D' Mello Road, CST, Mumbai	Institutional Ethics Committee, Grant Govt Medical College, JJ Road, JJ Hospital Compound, Mumbai, Maharashtra-400008, India ECR/382/Inst/MH/2013/RR-19	Dr. Akash Ashokkumar Khobragade
3.	Government Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India	Institutional Ethics Committee, Department of Pharmacology, Government Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Pande Abhishek Rajendrakumar
4.	Government Medical College, Panchakki Road, Aurangabad-431001, Maharashtra, India	Institutional Ethics Committee, Department of Pharmacology, Government Medical College, Aurangabad - 431001, Maharashtra, India ECR/440/Inst/MH/2013/RR-19	Dr. Meenakshi Bhattacharya
5.	BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India	BAPS Pramukh Swami Hospital Institutional Ethics Committee, BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India ECR/639/Inst/GJ/2014/RR-20	Dr. Koradia Parshottam Govindbhai
6.	Rhythm Heart Institute- A Unit of Synergy Lifecare-Pvt. Ltd., Near Siddharth Bunglows, Sama-Savli Road, Vadodara-390022, Gujarat	Rhythm Heart Institute Ethics Committee, Near Siddharth Bunglows, Sama-Savli Road, Vadodara-390022, Gujarat ECR/224/Inst/GJ/2013/RR-19	Dr. Nirav Chandulal Bhalan
7.	Clinical Research Room, Department of General Medicine, King George Hospital, Rajendra Prasad Ward, Maharanipeta, Visakhapatnam-530002	IEC King George Hospital, King George Hospital, Maharanipeta, Collector Office Junction, Visakhapatnam-530002, Andhrapradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. Yandrapati Gnana Sundara Raju

8.	Star Synergy Hospital-A Unit of Saurashtra Medicare LLP, Opp. Vishveshwar Temple, Mavdi Main Road Rajkot-360004, Gujarat, India	Synergy Hospital Ethics Committee, Synergy Superspeciality Hospital, 150 Feet Ring Road, Opposite Gokul Mathura Apartments, Ayodhya Chowk Rajkot, Gujarat-365005, India ECR/1178/Inst/Guj/2019	Dr. Jayeshkumar Avacharbhai Dobariya
9.	Shetty's Hospital, Plot No. 11 & 12, 12th "F" main Kaveri Nagar, Bommanahalli, Kodichikkanahalli, Bangalore-560068, Karnataka	Shetty's Hospital Ethics Committee, Plot No. 11 & 12, 12th "F" Main Kaveri Nagar, Bommanahalli, Kodichikkanahalli, Bangalore-560068, Karnataka ECR/918/Inst/KA/2017/RR-20	Dr. S. Poorna Prasad
10.	Siddhi Hospital, P-67, MIDC, Satpur, Behind ITI, Trimbak Road, Nashik-422007, Maharashtra, India	Siddhi Hospital Institutional Ethics Committee (SHIEC), P-67, MIDC, Satpur, Behind PF Office, Trimbak Road, Nashik-422007, Maharashtra, India ECR/739/Inst/MH/2015/RR-18	Dr. Abhinandan Bhikchand Mutha
11.	Aman Hospital and Research Center 15, Shashwat, Opp. E.S.I Hospital, Gotri Road, Vadodara-390021, Gujarat, India	Institutional Ethics Committee Aman Hospital and Research Center, Aman Hospital and Research Center 15, Shashwat, Opp. E.S.I Hospital, Gotri Road, Vadodara-390021, Gujarat, India ECR/857/Inst/GJ/2016/RR-19	Dr. Aman Khanna
12.	Chopra Medicare and 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, C/o Chopra Medicare and 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 ECR/79/Inst/MH/2013/RR-19	Dr. Swapnil Suresh Sakhala
13.	JSS Hospital, M.G. Road, Mysuru-570004, Karnataka, India	Institutional Ethics Committee, 3rd floor, JSS Medical College, S.S Nagar, Mysuru. 570015. Karnataka. India. ECR/378/Inst/KA/2013/RR-19	Dr. Tejeswini C.J
14.	VHS Infectious Disease Medical Centre, Chennai Antiviral Research and Treatment (CART) Clinical Research Site, Voluntary Health	Institutional Ethics Committee, The Voluntary Health Services, multi-Speciality Hospital & Research Centre, Rajiv Gandhi Salai, Adyar, Chennai-60113	Dr. Nagalingeswara Kumarasamy

	Services, Rajiv Gandhi Salai, Taramani, Chennai-600113	ECR/752/Inst/TN/2015/RR-18	
15.	All India Institute of Medical Science, MIHAN, Sumthana, Nagpur-441108, Maharashtra, India	Institutional Ethics Committee, All India Institute of Medical Science, MlHAN, Sumthana, Nagpur-441108, Maharashtra, India ECR/1392/ Inst/MH/2020	Dr. Joshi Prashant Prabhakar
16.	Kamalnayan Bajaj Hospital, Gut No. 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, Maharashtra, India	Ethics Committee Kamalnayan Bajaj Hospital, Kamalnayan Bajaj Hospital, Gut No. 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, Maharashtra, India ECR/444/Inst/MH-2013/RR-20	Dr. Milind Vaishnav
17.	Durgabai Deshmukh Hospital & Research Centre, University Road, Vidyanagar, Hyderabad-500044, Telangana, India	Ethics Committee Durgabai Deshmukh Hospital & Research Centre, University Road, Vidyanagar, Hyderabad-500044, Telangana, India ECR/477/Inst/AP/2013/RR-20	Dr. M Sheetal Kumar