सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare 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/25/000070

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/2025/49835 dated 27-May-2025, please find enclosed herewith the permission in Form CT-06 for conduct clinical trial titled "**An Evaluation of Bemnifosbuvir-Ruzasvir (BEM/RZR) Versus Sofosbuvir-Velpatasvir (SOF/VEL) for the Treatment of Chronic Hepatitis C Virus (HCV) Infection in a Phase 3 Randomized, Controlled, Open-label Study" Protocol No.: AT-01B-008 version No. 2, amendment 1 dated 01-Apr-2025 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) EC approval shall be obtained before initiate the clinical trial.

(ii) Human biological samples i.e. Whole blood, plasma, serum and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

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

(xx) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(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,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.21 15:27:44 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

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.: AT-01B-008 version No. 2, amendment 1 dated 01-Apr-2025** 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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.21 15:28:02 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
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	Bemnifosbuvir+Ruzasvir
Therapeutic class:	Antiviral
Dosage form:	Tablets
Composition:	Bemnifosbuvir Hemisulfate=275.0000 milligram (mg) In House Specification Active Ruzasvir =90.0000 milligram (mg) In House Specification Active
Indications:	Hepatitis C Virus (HCV) infection

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
Amrita Institute OF medical scineces and Research centre, AIMS, Ponekkara POM Kochi Kerala - 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara, PO, Edappally, Ernakulam, Kochi-682041, Kerala, India. ECR/129/Inst/KL/20131RR-24	Dr Shine Sadasivan
Deenanath Mangeshkar Hospital and Research Centre, Department of Research, 6thFloor C Wing, Deenanath Mangeshkar Hospital and Research Centre, Off KarveRoad. Erandawane Pune Maharashtra - 411004	Institutional Ethics Committee, Deenanath Mangeshkar Hospital and Research Center, Off Karve Road, Erandwane, Pune - 411004, Maharashtra, India ECR/15/Inst/Maha/2013/RR-22	Dr Sachin Sudhakarroa Palnitkar

KRM Hospital and Research Centre, 3/92-93, Vijayant Khand Gomtinagar Uttar Pradesh - 226010	Institutional Ethics Committee, Atharva Multispeciality Hospital and Research Centre, H-4/Comm-2, Constuction Div -21, UP Avas Vikas Parishad, Sector E, Lucknow- 226003, Uttar Pradesh, India ECR/1241/Inst/UP/2019/RR-24	Dr Vineet Kumar Shukla
Centre for Clinical Research John C Martin Centre for Liver Research and Innovations, Institute of Liver and Digestive Sciences Campus, Sitala East, Sonarpur Kolkata West Bengal - 700150	Human Research Ethics Committee, Indian Institute of Liver & Digestive Sciences (HREC, IILDS), Sitala East, Malipukuria, Jagadishpur, Sonarpur South, 24 Parganas, Kolkata-700150, West Bengal, India ECR/1568/Inst/WB/2021	Dr Abhijit Chowdhury
Seth G. S. Medical College And King Edward Memorial Hospital, Department of Gastroenterology, Acharya Donde Marga, Parel Mumbai Maharashtra - 400012	Institutional Ethics Committee-I, Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai-400012, Maharashtra, India ECR/229/Inst/MH/2013/RR-24	Dr Arun Vaidya
B. Y. L. Nair Charitable Hospital and Topiwala National Medical College, College Building, A. L. Nair Road, Mumbai Central Mumbai Maharashtra - 400008	Institutional Ethics Committee, Topiwala National Medical College Nair Hospital, Dr A L Nair Road, Mumbai Central, Mumbai-400008, Maharashtra, India ECR/22/Inst/Maha/2013/RR-24	Dr Pravin Motilal Rathi
Midas Hospital, 392, Parsodi, Wardha Road Nagpur Maharashtra - 441108	Institutional Ethics Committee, Midas Multispeciality Hospital Pvt. Ltd, Midas Heights, 07, Central Bazar Road, Ramdaspeth, Nagpur-440010, Maharashtra, India ECR/494/Inst/MH/2014/RR-20	Dr Shrikant Vasantrao Mukewar

Postgraduate Institute of Medical Education and Research, Department of Gestroentrology, F- Block, Ground Floor, Nehru Hospital, Sector-12 Chandigarh Chandigarh - 160012	Post Graduate Institute of Medical Education and Research, Room No. 6006, IEC Office, 6th Floor, P N Chuttani Block, Chandigarh-160012, India EC/RENEW/INST/2020/7442	Dr Jayanta Samanta
SIDS Healthcare Private Limited, SIDS Hospital and Research Centre - A Multi Super-Speciality Hospital, Off Ring Road, Near Shell Petrol Pump, Ring Road Surat Gujarat - 395002	Surat Institute of digestive sciences EC, Surat Institute of digestive sciences A unit of SIDS healthcare Pvt. Ltd, J J Empire Vijay Nager-3, Beside Nirmal Bhavan, Majura Gate, Surat-395002, Gujarat, India ECR/813/Inst/GJ/2016/RR-24	Dr Rajiv Manhar Mehta
Lifepoint Multispeciality Hospital, Sr. No. 145-1, Mumbai Bangalore Highway, Near Hotel Sayaji, Bhumkar Chowk, Wakad Pune Maharashtra - 411057	Lifepoint Research-Ethics Committee Life Point Mutispecialty Hospital Pvt. Ltd.145/1, Mumbai-Bangalore highway Near Hotel Sayaji Wakad Pune Maharashtra - 411057 India ECR/751/Inst/MH/2015/RR-21	Dr Sachin Kisan Shivnitwar
Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna Bihar - 80014	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Raja Bazar, Patna-800014, Bihar, India ECR/640/Inst/BR/2014/RR-20	Dr Manish Mandal
Atal Institute of Medical Super Specialities, Department of Gastroenterology Shimla Himachal Pradesh - 171006	Institutional Ethics Committee, Indira Gandhi Medical College, Shimla - 171001, Himachal Pradesh, India ECR/533/Inst/HP/2014/RR-20	Dr Brij Sharma
G. S. V. M. Medical College, Swaroop Nagar Kanpur Uttar Pradesh - 208002	Ethics Committee, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh ECR/680/Inst/UP/2014/RR-20	Dr Vinay Kumar

Shree Giriraj Multispeciality Hospital, A unit of Shree Giriraj Lifecare Pvt Ltd, 27-Navjyot Park, 150 Feet Ring Road Rajkot Gujarat - 360005	Shree Giriraj Hospital Research Ethics Committee, Shree Giriraj Multispeciality Hospital, 27-Navjyot Park Main Road, Amin Marg Cross Road, Rajkot-360005, Gujarat, India ECR/74/Inst/GJ/2013/RR-19	Dr Chetan Nalin Mehta
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, J. N. Medical College, Nehru Nagar Belagavi Karnataka - 590010	Institutional Ethics Committee, KLE Academy of Higher Education and Research (KAHER), Belagavi JNMC Campus, Nehru Nagar Belagavi-590010, Karnataka India ECR/211/Inst/KA/2013/RR-24	Dr Santosh Dhananjay Hajare
Gujarat Hospital-Gastro and Vascular Centre, Opposite Shree Ram Petrol Pump, Anand Mahal Road, Adajan Surat Gujarat - 395009	Unity Hospital Ethics Committee, Unity Trauma Center And ICU, N-4 Janki Park Society, Aai Mata Road, Paravat Patiya, Surat-395010, Gujarat, India ECR/1226/Inst/GJ/2019/RR-24	Dr Saumin Prakashbhai Shah
Banaras Hindu University, Institute of Medical Sciences Varanasi Uttar Pradesh - 221005	Institutional Ethics Committee, Institute of Medical Sciences, Banaras Hindu University Varanasi- 221005, Uttar Pradesh, India ECR/526/Inst/UP/2014/RR-20	Dr Dewesh Prakash Yadav
Yashoda Hospitals, Yashoda Healthcare Services PVT. LTD, S.P Road, Secunderabad Telangana - 500003	Yashoda Academy of Medical Education and Research, Yashoda Hospitals, Behind Hari Hara Kala Bhawan, Alexander Road, Secunderabad - 500003, Telangana, India. ECR/49/Inst/AP/2013/RR-22	Dr B Ravi Shankar
Samvedna Hospital, B-27-88G, Ravindrapuri Varanasi Uttar Pradesh - 221005	Samvedna Hospital Ethics Committee, Samvedna Hospital, B-22l88 G New Ravindra Puri Colony Varanasi- 221005, Uttar Pradesh, India	Dr Hemant Kumar Gupta

	ECR/45/Inst/U P/2013/RR-20	
Sarojini Naidu Medical College, Central Library, Moti Katra Agra Uttar Pradesh - 282003	Institutional Ethics Committee, S.N Medical S N Medical College, Raja Mandi Near Agra College, Agra Central Library, moti Katra, Mantola, Agra-282003,Uttar Pradesh, India ECR/526/Inst/UP/2014/RR-20	Dr Prabhat Kumar Agrawal
Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines Ludhiana Punjab -141001	Drug Trial Ethics Committee Dayanand Medical College and HospitalTagore Nagar, Civil Lines, Ludhiana- 141001, Punjab, India ECR/101/Inst/PB/2013/RR-24	Dr Omesh Goyal

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