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/25/000052

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/2025/49488 dated 09-May-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled "**EASi-HF reduced – A Phase III double-blind, randomised, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat (BI 690517) and empagliflozin compared with placebo and empagliflozin in participants with symptomatic chronic heart failure (HF: NYHA II-IV) and left ventricular ejection fraction (LVEF) < 40%" Protocol no. 1378-0018 version No. 1.0 dated 14 Jan 2025 with a total of up-to 121 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) Hyperkalemia should be strictly monitor during the study.
(iii) 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.
(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) 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;

(xxii) 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

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Date: 2025.10.21 17:31:34 +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. 1378-0018 version No. 1.0 dated 14 Jan 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

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Date: 2025.10.21 17:31:42 +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	vicadrostat (BI 690517)
Therapeutic class:	Antihypertensive
Dosage form:	Film coated tablets
Composition:	BI 690517 XX =10.0000 milligram (mg) In House Specification Active
Indications:	Treatment of symptomatic chronic heart failure (HF: NYHA II-IV) and left ventricular ejection fraction (LVEF) < 40%

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
S.P Medical College & A.G Hospitals, HRMC Cardiovascular Sciences & Research Centre Bikaner Rajasthan -334001	Ethics Committee, S.P. Medical College, Pawanpuri, Bikaner - 334003, Rajasthan, India ECR/27/SP/Inst/RJ/2013/RR-19	Dr Dinesh Choudhary
Apollo Hospitals, Apollo Hospitals (Apollo Health City) Jubliee Hills Hyderabad Andhra Pradesh -500096	Institutional Ethics Committee-Clinical Studies Apollo Hospitals Enterprises Limited, No-21, Greams Lane off Greams road, Chennai -600006, Tamil Nadu, India ECR/37/Inst/TN/2013/RR-19	Dr Abraham Oomman
Lisie Hospital, Kochi-682018 Kerala India	Institutional ethics Committee, ECR/40/Inst/KL/2013/RR-25	Dr Jabir abdullakutty

Magna-Care Ethics committee, Magnum Heart Institute, C/O Chopda Medicare & Research Centre Pvt Ltd., Patil Lane No: 1, Near K.B.H Vidalaya Canada Corner, Nashik Maharashtra	Magna-Care Ethics Committee ECR/79/Inst/MH/2013/RR-24	Dr Manojkumar Bhavarilal Chopada
Max Super Speciality Hospital, 6 floor, Press Enclave Road, Saket New Delhi Delhi - 110017	Institutional Ethics Committee, Devki Devi Foundation ECR/110/Inst/DL/2013/RR-24	Dr Vijay Kumar Chopra
IPGME&R Research Oversight Committee, C/o Office of the Dean college Buidling, 5Th Floor Institute of Postgraduate Medical Education & Research 244 Acharya J.C. Bose Road West Bengal - 700020	IPGME and R Resaerch Oversight Committee, IPGME and R, 244 Acharya J. C. Bose Road, Kolkata -700020, West Bengal, India ECR/35/Inst/WB/2013/RR-24	Dr Saroj Mandal
King George Hospital, Institutional Ethics committee King George Hospital Visakhapatnam Andhra Pradesh - 530002	IEC King George hospital, King George Hospital, Mahranipeta, Collector office Junction, Visakhapatnam-530002 Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr Jenny Madhuri Gudivada
Supe Hospital, Supe Hospital Ethics committee (SHEC) Supe Heart and Diabetes Hospital and Research centre , Opposite Adharashram Gharpure Ghat Near Rungta High School, Ashok Stambh Nasik Maharashtra - 422002	Supe Hospital Ethics Committee ECR/272/Inst/MH/2013/RR-24	Dr. Girish Bachhav
Medanta Institute of Education and Research Regulatory ,Medanta Institute of Education and Research Regulatory office, IInd Floor, Opposite Medical Library, Training Block, Medanta- The Medicity, Sector-38, Gurgaon Haryana -122001	Medanta Institutional Ethics Committee, Medanta-The Medicity, Sector 38, Gurugram-122001, Haryana, India ECR/282/Inst/HR/2013/RR-20	Dr Sanjay Mittal

Nirmal Hospital Private, Nirmal Hospital Private Ethics Committee, Ring Road, Surat Gujarat - 395002	Nirmal Hospital Pvt Ltd Ethics Committee ECR/390/Inst/GJ/2013/RR-24	Dr Atul Damodar Abhyankar
Narayana Hrudayalaya Medical, Narayana Hrudayalaya Medical Ethics Committee (NHMEC), NH Health City, No. 258/A, Bomasandra Industrial Area, Anakal Taluk, Bangalore Karnataka - 560099	Narayana Health Medical Ethics Committee, Narayana Health Hospital, Health City, No. 258/A, Bommasandra Industrial Area Anekal Taluk, Bengaluru (Bangalore) Rural -560099, Karnataka, India ECR/390/Inst/KA/2013/RR-24	Dr Venkatachalagupta, Srikanth
Kamalnayan Bajaj Hospital, Ethics Committee, Kamalnayan Bajaj Hospital, Situated at GUT. NO. 43, Satara Parisar, Bajaj Marg, Beed By-Pass Road, Aurangabad Maharashtra - 431005	Ethics Committee, Kamalnayan Bajaj Hospital, Gut No.43, Satara Parisar, Beed By-pass Road Aurangabad - 431010, Maharashtra, India ECR/444/Inst/MH/2013/RR-24	Dr Ajit Raghunath Bhagwat
Indira Gandhi Institute of Medical Sciences (IGMS), Ethics Committee, Indira Gandhi Institute of Medical Sciences (IGMS), Sheikhpura, Patna Bihar - 800014	Institutional Ethics Committee ECR/640/Inst/BR/2014/RR-20	Dr Ravi Vishnu Prasad
Unicare Heart Institute and Research Center, Acme Plaza, B- Wing, Near Sosyo Circle, BH New Civil Hospital, Canal Road Surat Gujarat - 395002	UNITY HOSPITAL ETHICS COMMITTEE ECR/1226/Inst/GJ/2019/RR-24	Dr Devang kumar Mahesh chandra Desai
Tamil Nadu Government Multi Super Specialty Hospital, Omandurar Estate ChennaiTamil Nadu - 600002	Institutional Ethics Committee, TNGMSSH, Tamil Nadu Govt. Multi Super Specialty Hospital, Omandurar Govt Estate Anna Salai, Chennai -600002, Tamil Nadu, India ECR/1375/Inst/TN/2020	Dr Cecily Mary Majella

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