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/25/000088

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/2025/50347 dated 25-Jun-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled "**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 type 2 diabetes, hypertension and established cardiovascular disease" Protocol No. 1378-0041 version 1.0 dated 02 May 2025 with a total of up-to 100 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) Carcinogenicity study report shall be submit once the study completed.

(ii) Human biological samples i.e. Whole blood 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: 2025.10.29 15:46:31 +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. 1378-0041 version 1.0 dated 02 May 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: 2025.10.29 15:46:40 +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:	type 2 diabetes, hypertension and established cardiovascular disease

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
Sir Ganga Ram Hospital Ethics Committee, Room No 1496. IV Floor , Old Building, Old Rajinder Nagar New Delhi Delhi - 110060	Sir Ganga Ram Hospital Ethics Committee ECR/20/Inst/DL/2013/RR-24	Dr Ashwani Mehta
S.P Medical College & A.G Hospitals, HRMC Cardiovascular Sciences & Research Centre Bikaner Rajasthan - 334001	ETHICS COMMITTEE, S.P. MEDICAL COLLEGE ECR/27/SP/Inst/RJ/2013/RR-19	Dr Pintu Nahata
Magna-Care Ethics committee, Magnum Heart Institute, C/O Chopda Medicare &Research Centre Pvt Ltd., PatilLane 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-19	Dr Vijay Kumar Chopra
Deenanath Mangeshkar Hospital and Research Centre, Department of Research, 6thFloor C Wing, Deenanath Mangeshkar Hospital and Research Centre, Off Karve Road. Erandawane Pune Maharashtra - 411004	Institutional Ethics committee ECR/15/Inst/Maha/2013/RR-22	Dr Vaishali Chetan Deshmukh
King George Hospital, institutional Ethics committee King George Hospital Visakhapatnam Andhra Pradesh - 530002	IEC King George hospital ECR/197/Inst/KGH/2013/RR-20	Dr Jenny Madhuri Gudivada
Sunil ‘s Diabetes Care n’ Research Centre , Institutional Ethics Committee Sunil ‘s Diabetes Care n’ Research Centre 42, Lendra Park Ramdaspeth Nagpur Maharashtra - 440010	Ethics Committee of Sunil’s Diabetes Care n Research Centre ECR/1951/Inst/MH/2024	Dr Sunil Gupta
Batra Hospital and Medical Research Centre, Dr Neelam Khanna MBBS, MD , MNAMS Senior consultant, Microbiology Mmeber secretary, Scientific Research and Ethical Review Committee Department of Laboratory Medicine Batra Hospital and Medical Research Centre 1, Tuglakabad Insitutional Area MB Road New Delhi Delhi - 110062	Scientific Research and Ethical review Committee ECR/295/Inst/DL/2013/RR-22	Dr Upendra Kaul
Bangalore Medical college and Research Institute, Ethics committee of Banglaore Medical College and Research Institute 1st Floor, Banglore Medical college and Research	ETHICS COMMITTEE OF BMCRI ECR/302/Inst/KA/2013/RR-20	Dr Divyaprakash Mada

Institute K.R Road, Fort, Banglore Karnataka - 560002		
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
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 ECR/444/Inst/MH/2013/RR-24	Dr Ajit Raghunath Bhagwat
Jothydevs Diabetes Research Centre, JDC Junction Konkalam Road Mudavanmugal Kerala	Institutional Ethics Committee ECR/1167/Inst/KL/2019/RR-22	Dr Jothydev
Apollo Multispeciality Hospitals limited, 58, Canal Circular Road Kolkata West Bengal - 700054	Institutional Ethics Committee ECR/373/Inst/WB/2013/RR-19	Dr Tirthankar Chaudhury
G.B. Pant Institute of Postgraduate Medical Education and Research, Jawahar Lal Nehru Marg New Delhi Delhi - 110002	INSTITUTIONAL ETHICS COMMITTEE MAMC ECR/329/INST/DL/2013/RR-24	Dr Vimal Mehta
Gujarat Endocrine Centre-aunit of Gujarat Endocrine Pvt Ltd, 518-526 AWS-3 BLOCK B Opp Manav Mandir, Nr Helmet Cross Road Ahmedabad Gujarat - 380052	Sangini Hospital Ethics Committee ECR/147/Inst/GJ/2013/RR-24	Dr Parag Shah
LPS Institute of Cardiology, GSVM Medical College Swaroop nagar Kanpur UttarPradesh - 208002	ETHICS COMMITTEE GSVM MEDICAL COLLEGE, Kanpur	Dr Awadhesh Kumar Sharma

	ECR/680/Inst/UP/2014/RR-20	
Fortis Escorts Heart Institute, Okhla Road New Delhi Delhi - 110025	INSTITUTIONAL ETHICS COMMITTEE ECR/261/Inst/DL/2013/RR-24	Dr Vishal Rastogi
Rabindranath Tagore International Institute of Cardiac Sciences, Premises No 1489124 Mukundapur, E. M. Bypass Kolkata West Bengal - 700099	NHRTIICS Ethics Committee ECR/316/Inst/WB/2013/RR-24	Dr Debmalya Sanyal

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