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/24/000059**

To,

M/s GEORGE INSTITUTE SERVICES INDIA PRIVATE LIMITED,
409, Elegance Tower, Plot No. 8, Jasola District Centre Sukhdev Vihar,
South Delhi, New Delhi, Delhi, India, 110025 New Delhi (India) -110025

Sir,

With reference to your application No. GCT/CT04/FF/2024/42897 dated 15.04.2024, please find enclosed herewith the permission in Form CT-06 for conduct of **Phase III** clinical trial titled, **"A multicenter, international, randomized, double-blind, placebo-controlled clinical trial of the aldosterone synthase inhibitor BI 690517 in combination with empagliflozin in patients with chronic kidney disease (EASi-KIDNEY)" Protocol No.: 1378-0006 Version No. 1 Protocol Date 12-MAR-2024 with a total of up-to 1250 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) Final carcinogenicity study reports should be submitted to CDSCO.**

**(ii) Human biological samples i.e. Blood samples, Serum samples, Urine samples, and Plasma samples related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**

**(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.

RAJEEV SINGH RAGHUVANSHI

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Date: 2024.11.11 17:22:55 +05'30'

Yours faithfully,

(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 GEORGE INSTITUTE SERVICES INDIA PRIVATE LIMITED, 409, Elegance Tower, Plot No. 8, Jasola District Centre Sukhdev Vihar, South Delhi, New Delhi, Delhi, India, 110025 New Delhi (India) -110025** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: 1378-0006 Version No. 1 Protocol Date 12-MAR-2024** 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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(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:

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| **Names of the new drug or investigational new drug** | BI 690517 |
| **Therapeutic class:** | Aldosterone Synthase Inhibitor |
| **Dosage form:** | Tablets |
| **Composition:** | BI 690517 XX =10.0000 milligram (mg) In House Specification Active |
| **Indications:** | Chronic Kidney Disease |

**Annexure:**

Details of clinical trial site:

| Sr. No. | Names and address of clinical trial site | Ethics committee details | Name of investigator |
|---|---|---|---|
| **1.** | 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 | Dr Vinant Bhargava |
| **2.** | Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Attn:Prof Dheeraj Gupta, Sector 12 Chandigarh Chandigarh - 160012 | Institutional Ethics Committee Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor P N Chuttani Block Chandigarh,160012 ECR/25/Inst/CH/2013/RR-20 | Dr Vivek Kumar |
| **3.** | Max super speciality Hospital, Press enclave Raod, Saket New delhi Delhi - 110017 | Max Healthcare Ethics Committee Ground floor, Office of Ethics Committee, West Block, Near MS Office, Max Super Speciality Hospital, No. 1, Press Enclave Road, Saket, New Delhi, 110017<br><br>ECR/118/Inst/DL/2013/RR-19 | Dr Dinesh Khullar |
| **4.** | Yashoda Hospital, Behind Harihara, Kala Bhawan Secunderabad Andhra Pradesh- 500007 | Yashoda Academy of Medical Education and Research Yashoda Hospitals Behind Hari Hara kala Bhawan SP Road Secunderabad, Hyderabad Telangana -500003<br><br>ECR/49/Inst/AP/2013/RR-22 | Dr Tarun Kumar Saha |
| **5.** | Fortis ft lt Rajan Dhall Hospital, sector -B, Pocket-1, Aruna Asf Ali Marg, VASANTKUNJ New Delhi Delhi -110070 | Ethics Committee for Research Fortis Flt Lt. Rajan Dhall Hospital Sector-B Pocket-1 Aruna Asaf Ali Marg Vasant Kunj New Delhi, Delhi -110070<br><br>ECR/57/Inst/DL/2013/RR-19 | Dr Sanjeev Gulati |
| **6.** | St. John's Medical College, Instituional Ethical review Board (IERB) Ground Floor , St. John's Medical College Sarjapur Road, Bnagalore Karnataka - 560034 | Institutional Ethics Committee St. Johns Medical College Hospital Sarjapur Road Koramangala Bengaluru (Bangalore) Urban Karnataka - 560034<br><br>ECR/238/Inst/KA/2013/RR-19 | Dr Anantharam Jairam |

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| **7.** | Osmania medical college, Osmania medical college, Koi, Hyderabad Telangana - 500095 | Institutional Ethics Committee Osmania Medical College Osmania Medical College, Koti, Hyderabad,Telangana - 500095<br><br>ECR/300/Inst/AP/2013/RR-19 | Dr Manisha Sahay |
| **8.** | Apollo Hospitals, 154/11, Opp. IIM, Bannerghatta Road, Bangalore Karnataka - 560076 | Institutional Ethics Committee-Clinical Studies Apollo Hospitals, Bengaluru 154/11, Opp. IIM, Bannerghatta Road Bengaluru Bengaluru (Bangalore) Urban Karnataka – 560076<br><br>ECR/320/Inst/KA/2013/RR-20 | Dr Prashant C Dheerendra |
| **9.** | Christian Medical College, Research Office, First Floor, Carman Block, Christian Medical College, Vellore Tamil Nadu - 632002 | Institutional Review Board, Christian Medical College, Thorapadi, Post Bagayam, Vellore, Tamil Nadu-632012<br><br>ECR/326/Inst/TN/2013/RR-19 | Dr Vinoi George David |
| **10.** | Kims Ethics Committee Situated at Office of Principal, Kims Ethics Committee Situated at Office of Principal, Karnataka Institute of Medical Sciences, Hubli Karnataka -580021 | Ethics Committee Of BMCRI Bangalore Medical College And Research Institute Fort K R Road Bengaluru (Bangalore) Urban Karnataka -560002<br><br>ECR/302/Inst/KA/2013/RR-20 | Dr Venkatesh Mogar |
| **11.** | All India Institute of Medical Sciences, Ethics Committee All India Institute of Medical Sciences situated at Village Sijua, Patrapada, PO Dumduma, Bhubaneshwar Orissa - 751019 | INSTITUTIONAL ETHICS COMMITTEE, AIIMS Bhubaneswar All India Institute Of Medical Sciences, BBSR AIIMS Bhubaneswar Sijua P/O Patrapada Bhubaneswar Khordha Orissa -751019<br><br>ECR/534/Inst/OD/2014/RR-20 | Dr Priti Meena |
| **12.** | All India Institute of Medical Sciences, Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1stFloor, Old O.T. Block, Ansari Nagar, New Delhi Delhi -110029 | Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 South Delhi Delhi -110029<br><br>ECR/538/Inst/DL/2014/RR-20 | Dr Sandeep Mahajan |

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| **13.** | Indira Gandhi Institute of Medical Sciences (IGMS), Ethics Committee, Indira Gandhi Institute of Medical Sciences (IGMS), Sheikhpura, Patna Bihar - 800014 | Institutional Ethics Committee, IGIMS, Sheikhpura Indira Gandhi Institute Of Medical Sciences Sheikhpura Raja Bazar Patna, Bihar -800014<br><br>ECR/640/Inst/BR/2014/RR-20 | Prof Om Kumar |
| **14** | Institute All India Institute of Medical Sciences, Institute Ethics Committee, All India Institute of Medical Sciences, Department of Pharmacology, 2nd Floor, South Wing, Medical College Complex, Gate No. 5, Tatibandh, GE Road, Raipur Chhattishgarh - 492099 | INSTITUTE ETHICS COMMITTEE, AIIMS Raipur Room No. 2103, 2nd Floor South Wing Medical College Complex, Gate No. 5 All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, Raipur-492099, Chhattisgarh<br><br>ECR/714/Inst/CT/2015/RR-21 | Dr Vinay Rathore |
| **15.** | Dr. Ram Manohar lohia Institute of Medical Sciences, Research Cell Office Room No.35 2nd Floor Administrative Block, RMLIMS Lucknow Uttar Pradesh - 226010 | Institutional Ethics Committee Dr. Ram Manohar Lohia Institute of Medical Sciences Research Cell Office Room No. 35 2nd Floor Administrative Block, RMLIMS Lucknow, Uttar Pradesh - 226010<br><br>ECR/913/Inst/UP/2017/RR-20 | Dr Namrata Rao S |
| **16.** | Atal Bihari Vajpayee Institute of Medical Sciences and Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, Near Gurudwara Bangla Sahib, Connaught Place, New Delhi Delhi - 110001 | Ethics Committee, PGIMER, Dr. Ram Manohar Lohia Hospital, New Delhi Baba Kharak Singh Marg, New Delhi Central Delhi – 110001<br><br>ECR/78/Inst/DL/2013/RR-19 | Dr Himanshu Sekhar Mahapatra |
| **17.** | All India Institute of Medical Sciences, Bilaspur, Changar Palasiyan, Noa Changar Palasiyan Himachal Pradesh -174001 | Institutional Ethics Committee Clinical Trials All India Institute Of Medical Sciences All India Institute Of Medical Sciences Village Kothipura Bilaspur Bilaspur Himachal Pradesh – 174037<br><br>ECR/1808/Inst/HP/2023 | Dr Sanjay Vikrant Sharma |
| **18.** | KIMSHEALTH Hospital, KIMSHEALTH Hospital, 1, Vinod Nagar Rd, Anayara, Thiruvananthapuram, | Institutional Human Ethics Committee KIMSHEALTH PB.No.1 Anayara Trivandrum Thiruvananthapuram Kerala - 695029 | Dr Satish Balan |

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| | Kerala 695029 Thiruvananthapuram Kerala - 695029 | ECR/184/Inst/Ker/2013/RR-22 | |
| **19.** | IQRAA International Hospital and Research Centre, Wayanad Rd, Malaparamba, Kozhikode, Kerala 673009 Kozhikode Kerala - 673009 | IEC-IQRAA International Hospital Research Center, Malaparamba Kozhikode Calicut -673009<br><br>ECR/18/Inst/KL/2013/RR-19 | Dr Shabna Sulaiman |
| **20.** | Manipal Hospitals, Baner, Survey No 111 11 1, Veerbhadra Nagar Rd, Mhalunge Main Road, Baner, Pune, Maharashtra 411045 Pune Maharashtra - 411045 | Ethics committee Manipal Hospital Baner Pune, Manipal Hospitals, Baner-Mhalunge Main Road, Baner, Pune, Maharashtra -411045<br><br>ECR/1825/Inst/MH/2023 | Dr Tarun Jeloka |
| **21** | All India Institute of Medical Sciences, Mandi Dabwali Rd, Bathinda, Punjab 151001 Bhatinda Punjab - 151001 | Institutional Ethics Committee, AIIMS, Bathinda All India Institute Of Medical Sciences, Bathinda Jodhpur Romana, Mandi Dabwali Road, Bathinda Punjab -151001<br><br>ECR/1466/Inst/PB/2020 | Dr Saurabh Nayak |

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