



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) PhoneNo.:
91-11-23216367
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File No. CT/20/000022

To,

M/s Covance India Pharmaceuticals Services Pvt. Ltd.,
S2, 424, 425, Level 4, MBC Park, Kasarwadavli,
Ghodbunder Road, Thane (West), Maharashtra - 400615, India.

Sir,

With reference to your application No GCT/CT04/FF/2020/19026 (GCT/89/17) dated 16- 03-2020 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function", Protocol number EFC14875 Version number 01 dated 29/08/2018** 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) 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 Licensing Authority under rule 8;
- (ii) 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;
- (iii) 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;
- (iv) the Central Licensing 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;
- (v) 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;
- (vi) 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;

- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvi) 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;
- (xvii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) 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
GIRDHARILA
L SOMANI

Digitally signed by VENUGOPAL
GIRDHARILA SOMANI
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ou=CDSCO DGH, postalCode=401 401,
email=venugopal.girdharila.somani@cdco.gov.in,
c=IN, o=Ministry of Health and Family Welfare,
ou=Ministry of Health and Family Welfare,
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Date: 2020.04.28 16:30:56 +05'30'

(Dr. V.G. Somani)

Drugs Controller General (India)
Central Licensing 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. Covance India Pharmaceuticals Services Pvt. Ltd., S2, 424, 425, Level 4, MBC Park, Kasarwadavli, Ghodbunder Road, Thane (West), Maharashtra - 400615, India THANE (India) – 400615** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number EFC14875 Version number 01 dated 29/08/2018** 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 _____

VENUGOPAL
GIRDHARILA
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Date: 2020.04.28 16:31:11 +05'30'

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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Sotagliflozin
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Sotagliflozin = 200.0000 milligram (mg) in House Specification Active
Indications:	Diabetes

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Department of Endocrinology, Osmania General Hospital, Osmania Medical College, Afzalgunj, Hyderabad, Telangana, India	Institutional Ethics Committee, Osmania Medical College ECR/300/Inst/AP/2013/RR-1	Dr. Rakesh Sahay
Eternal Hospital, A unit of Eternal Heart Care Centre & Research Institute Pvt Ltd. 3A, Jagatpura Road, Near Jawahar Circle, Jaipur- 302017, Rajasthan, India	Institutional Ethics Committee, Eternal Heart Care Centre & Research Institute ECR/615/Inst/RJ/2014/RR-17	Dr. Jugal B Gupta
Artemis Hospitals, Sector-51, Gurgaon-122001, Haryana	Artemis Health Sciences-Institutional Ethics Committee ECR/53/Inst/HR/2013/RR-16	Dr. Manjinder Singh Sandhu
Medanta-The Medicity, Sector- 38, Gurgaon, Haryana- 122001, India	Medanta Institutional Ethics Committee ECR/282/Inst/HR/2013/RR-1	Dr. Mittal
KLES Dr Prabhakar Kore Hospital and Medical research Centre, Nehrunagar ,Belagavi- 590010 Karnataka-India	Institutional Ethics Committee, KLE University ECR/211/Inst/KA/2013/RR-2016	Dr. Prasad MR
Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab-India- 141008	Institutional Ethics Committee, C/O Principal Office, Christian Medical College and Hospital ECR/120/Inst/PB/2013/RR- 16	Dr. Jubbin Jagan Jacob
Maxcure Hospitals, 5-9-22, Secretariat Road, Hydrebad- 500 063, Telangana State, India	Institutional Ethics Committee, Maxcure Hospitals ECR/832/Inst/TG/2016	Dr. Sridhar Papani
Department of Endocrinology, St.John's Medical College & Hospital, Sarjapur Road, Koramangala, Bangalore- 560034, Karnataka, India	Institutional Ethics Committee, St. John's Medical College ECR/238/Inst/KA/2013/RR-16	Dr. Ganapathi Bantwal
Niramaya hospital Pvt. Ltd, Chinchwad East, Post Office Road, Old Mumbai-Pune Highway, Pimpri- Chinchwad, Pune, Maharashtra- 411019	Nirmaya Hospital Ethics Committee ECR/438/Inst/MH/2013/RR-16	Dr. Abhijeet Joshi
Department of Cardiology, Super Speciality Hospital, Government Medical College and Hospital, Tukdoji Square,	Institutional Ethics Committee, GMC Department of Pharmacology ECR/43/Inst/MH/2013/RR-16	Dr. Sunil Washimkar

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Nagpur- 440009, Maharashtra		
Meditrina Institute of medical Sciences, Central Bazar Road, 278, Ramdaspath, Nagpur-440010	Medtrinia Institute Ethics Committee ECR/608/Inst/MH/2014/RR-17	Dr. Pankaj Harkut
The BM Birla Heart Research Centre 1/1, National Library Avenue, Kolkata-700027, West Bengal, India	B.M Birla Heart Research Center Institutional Ethics Committee ECR/55/Inst/WB/2013/RR-16	Dr. Dhiman Kahali
K.E.M Hospital and Seth G.S Medical College, Acharya Donde Marg, Parel, Mumbai 400012, Maharashtra, India	Institutional Ethics Committee ECR/229/Inst/MH/2013/RR-16	Dr. Prafulla Kerkar
Jehangir Clinical development Centre Pvt. Ltd. Jehangir Hospital Premises, 32 Sassoon road, Pune 411001, Maharashtra, India	Ethics Committee Jehangir Clinical development Centre Pvt. Ltd. ECR/352/Inst/MH/2013/RR-1	Dr. Mohan Magdum
Christian Medical College 810, Dept of Endocrinology Diabetes and Metabolism, Vellore-4, India. TN.632004	Ethics Committee – Silver, Institutional Review Board ECR/326/Inst/TN/2013/RR16	Dr. Nitin Kapoor
Chopda Medicare & Research Centre Pvt, Ltd; Magnum Heart Institute; 3/5 Patil Lane No. 1, Laxmi Nagar, Near K.B.H Vidyalaya, Canada Corner, Nashik-422005	Magna Care- Ethics Committee ECR/79/Inst/MH/2013/RR-16	Dr. Chopada Manojkumar Bhavarilal
Department of Endocrinology, Fortis Hospital Sector-62, Phase VIII, Mohali 160062	Institutional Ethics Committee ECR/28/Inst/PB/2013/RR-16	Dr. Kiran Singh Pal
Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara, P.O, Kochi, Kerala-682041, India	Institutional Ethics Committee ECR/129/Inst/KL/2013/RR-16	Dr. Harish Kumar
SAL Hospital & Medical Institute Opp. Doordarshan Tower , Drive-in Road, Thaltej Ahmedabad 380054, Gujarat, India	Institutional Ethics Committee, SAL Hospital & Medical Institute ECR/337/Inst/GJ/2013/RR-16	Dr. Anil Jain
Omega Hospital Mahaveer Circle, Kankanady, Mangalore 575002, Karnataka, India	Omega Ethical Committee ECR/89/Inst/KA/2013/RR-16	Dr. Mukund Kumbha
Yenepoya Medical College Hospital, Department of Internal Medicine, University Road, Deralakatte, Mangalore-575018	Yenepoya University Ethics Committee ECR/521/Inst/KA/2014/RR-17	Dr. Adhikari Prabha M.R

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Department of General Medicine, Government Medical College, Kozhikode-673008, Kerala, India	Institutional Ethics Committee ECR/395/Inst/KL/2013/RR-16	Dr. Neeraj Manikath
Maulana Azad Medical College Room No. 120, 1st Floor, Department of Medicine, B.L. Taneja Block, Maulana Azad Medical College, New Delhi -110002	Institutional Ethics Committee ECR/329/Inst/DL/2013/RR-16	Dr. Sandeep Garg
Maharashtra Medical Foundation, Joshi Hospital, 778, Shivaji Nagar, Opposite Kamala Nehru Park, Pune-411004	Institutional Ethics Committee ECR/311/Inst/MH/2013/RR-16	Dr. Nitin Patki
Columbia Asia No.85-86, Bangalore Mysore ring road junction, BanniMantap 'A' Layout, Siddiqui Nagar, Mondri Moholla, Mysore 570015	Institutional Ethics Committee ECR/134/Inst/KA/2013/RR-16	Dr. C. B. Keshavamurthy
Noble Hospital Pvt. Ltd, 153, Magarpatta City road, Hadapsar, Pune , Maharashtra, India- 411013	Institutional Ethics Committee ECR/259/Inst/MH/2013/RR-16	Dr. Aparna Nilesch Kodre
Mahatma Gandhi Mission Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India	Ethics Committee for Research on Human Subjects ECR/581/Inst/MH/2014/RR-16	Dr. Prashant Udgire
Department of Endocrinology & Metabolism, All India Institute of Medical Sciences, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee ECR/538/Inst/DL/2014/RR-17	Dr. R K Yadav
Deenanath Mangeshkar Hospital and Research Center, Erandwane, Pune – 411004, Maharashtra, India	Institutional Ethics Committee ECR/15/Inst/Maha/2013/RR-16	Dr. Vaishali Deshmukh