



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/24/000035

To,

M/s George Clinical India Pvt Ltd.,
Plot No. 5, Prestige Khoday Towers,
12th Floor Raj Bhavan Road,
Bengaluru (India) – 560001.

Sir,

With reference to your application No. GCT/CT04/FF/2024/42175 dated 07-Mar-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III clinical trial** titled, **“RandomizEd trial to DEtermine the efficacy and safety of FINerenone on morbidity and mortality among heart failure patients with left ventricular ejection fraction greater than or equal to 40% hospitalized due to an episode of acute decompensated Heart Failure (REDEFINE-HF)” Protocol No: 202301CPC version number 2.0 dated 03-October-2023 with a total of up-to 108 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) 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;
- (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 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;
- (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) 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;
- (xix) 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.

(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 Clinical India Pvt Ltd., Plot No. 5, Prestige Khoday Towers, 12th Floor Raj Bhavan Road Bengaluru (India) – 560001** to conduct clinical trial of the new drug or investigational new drug as per ” **Protocol No: 202301CPC version number 2.0 dated 03-October-2023** 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 _____

(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	BAY94-8862
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Finerenone 10 mg
Indications:	Acute decompensated Heart Failure

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, Room No 1496. IV Floor, Old Building, Old Rajinder Nagar New Delhi Delhi-110060	Sir Gangaram Hospital Ethics Committee Old Rajinder Nagar, New Delhi-110060 ECR/20/Inst/DL/2013/RR-19	Dr J P S Sawhney
2.	Lisie Hospital, Cochin Kerala-682018	Institutional Ethics Committee Lisie Hospital, Kochi, Kerala-682018 ECR/40/Inst/KL/2013/RR-20	Dr Jabir Abdulla Kutty
3.	Apollo Speciality Hospitals, 4 th Floor, Lakeview Road, KK Nagar Madurai Tamil Nadu -625020	Institutional Ethics Committee Appollo Hospitals Enterprises Ltd, Off Greems Road, Chennai-600006. ECR/37/Inst/TN/2013/RR-19	Dr Abraham Oomman
4.	Max superspeciality Hospital, Press enclave Raod, Saket New delhi Delhi-110017	Institutional Ethics Committee Max Super Speciality Hospital, Saket, New Delhi-110017 ECR/110/Inst/DL/2013/RR-19	Dr Vijay Kumar Chopra
5.	Sree Chitra Institute for Medical Sciences and Technology (SCTIMST), Institutional Ethics committee sree	Institutional Ethics Committee SCTIMST SCTIMST Medical College PO Thiruvananthapuram Thiruvananthapuram Kerala -	Dr Ramya Das NK

	chitratrirunal Institute for Medical Sciences and Technology Trivandaram Trivandaram Kerala-695011	695011 India ECR/189/Inst/KL/2013/RR-21	
6.	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	Institutional Ethics Committee Medanta-The Medicity, Gurugram, Haryana-122001 ECR/282/Inst/HR/2013/RR-20	Dr Praveen Chandra
7.	Christian Medical College, Research Office, First Floor, Carman Block, Christian Medical College, Vellore Tamil Nadu-632002	Institutional Ethics Committee CMC Vellore, Bagayyam, Vellore ECR/326/Inst/TN/2013/RR-19	Dr John Jose E
8.	Vardhman Mahavir Medical College & Safdarjung Hospital, Ethics Committee, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi Delhi-110029	Institutional Ethics Committee VMMC And SAFDARJUNG HOSPITAL Ring Road Ansari Nagar New Delhi South Delhi Delhi -110029 India ECR/593/Inst/DL/2014/RR-20	Dr Sandeep Bansal
9.	Indira Gandhi Institute of Medical Sciences (IGMS), Ethics Committee, Indira Gandhi Institute of Medical Sciences (IGMS), Sheikhpura, Patna Bihar-800014	Institutional Ethics Committee, IGIMS IGIMS, Sheikhpura, Patna-800014 ECR/640/Inst/BR/2014/RR-20	Dr Ravi Vishnu Prasad
10.	Sengupta Hospital & Research Institute, Ethics Committee, Sengupta Hospital & Research Institute, Ravinagar Square, Nagpur Maharashtra-440033	Institutional Ethics Committee Sengupta Hospital, Nagpur 440033 ECR/675/Inst/MH/2014/ RR-20	Dr Shantanu Sengupta
11.	Matis Multispeciality Hospital, Opposite Adani CNG Gas Station Near Motera BRTS Bus Stop, Cross Roads, Motera, Ahmedabad Gujarat-380005	Shakti Hospital Ethics Committee A116,117,118 And A 102,103,105 FF Krishna Complex Nr Shahwadi Bus Stand, Narol Ahmedabad Ahmedabad Gujarat -382405 India ECR/1766/Inst/GJ/2023	Dr Kamal H Sharma

12.	Fortis Hospital Mohali, Sector-62, Phase-8, SAS Nagar, Mohali, Punjab- 160062	Institutional Ethics Committee Fortis Hospital, Mohali, Punjab- 160062 ECR/28/nst/PB/2013/RR-19	Dr. Rajat Sharma
------------	--	--	------------------
