F. No.: ND/CT04/FF/2022/32904
dated 08.07.2022

Tele No.011-23236965
Fax.No.011-23236973

F. No. ND/CT/22/000048
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
24 AUG 2022

To

M/s. Bayer Pharmaceuticals Pvt. Ltd.,
Bayer House, Central Avenue,
Hiranandani Estate, Thane,
Maharashtra (India)- 400607.

Subject: Grant of permission to undertake Phase-IV Clinical Trial titled "A prospective, interventional, multicenter, Phase IV, open-label, single arm study to assess the safety and effectiveness of Finerenone in participants from India with chronic kidney disease associated with type 2 diabetes" - regarding.

CT NOC No.: CT/ND/41/2022

Sir,

With reference to your application no. ND/CT22/000048 dated 08.07.2022, please find enclosed herewith the permission in Form CT-06, No. CT/ND/41/2022 to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully,

(Dr. V. G. Somani)
Central Licensing Authority

Conditions of Permission

(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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 Licensing 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 utilized 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;

(xvi) The Central Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) It may kindly be noted that merely granting permission to conduct Clinical Trial study with the drug doesn't convey or imply that based Clinical Trial data generated with the drug, permission to market this drug will automatically be granted to you.

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

CT NOC No.: CT/ND/41/2022

The Central Licensing Authority hereby permits M/s. Bayer Pharmaceuticals Pvt. Ltd., Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra (India)- 400607 Telephone No.: 0222-5311234, Fax No. 0222-5455063, E-Mail: priya.chatterjee@bayer.com to conduct clinical trial of the **new drug** as per protocol no. **22224, version no. 1.0, dated 21.06.2022** in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Finerenone 10 mg and 20mg
Therapeutic class:	Aldosterone Antagonists Selective MRA
Dosage form:	Film coated tablets
Composition:	Each film-coated tablet contains Finerenone micronized..... 10mg /20 mg
Indications:	Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non fetal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) .

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number
1.	Dr Harbir Singh Kohli, 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 India. ECR/25/Inst/CH/2013/RR-20
2.	Dr M Edwin Fernando, Government Stanely Medical College and Hospital, Department of Nephrology Chennai Chennai Tamil Nadu - 600001	Institutional Ethics Committee Govt Stanley Medical College No.1, Old Jail Road, Royapuram, Chennai, Tamil Nadu -600001 India ECR/131/Inst/TN/2013/RR-22
3.	Dr Narayan Prasad, Sanjay Gandhi Post graduate Institute of Medical Sciences, SGPGI Bioethics Cell, Room No. 205, Ist Floor, Administrative Block Sanjay Gandhi Post graduate	INSTITUTIONAL ETHICS COMMITTEE Sanjay Gandhi Postgraduate Institute of M Sciences Raebareli Road Lucknow Uttar Pradesh -226014 India.

	Institute of Medical Sciences, Raebareli Road Lucknow Uttar Pradesh- 226014	ECR/16/Inst/UP/2013/RR-20
4.	Dr Dilip Kumar Pahari, Medica Superspecilaity Hospital, Clinical Research Ethics Committee Medica Superspeciality Hospital 127 Mukundapur , EM Bypass, Kolkata West Bengal - 700099	Clinical Research Ethics CommitteeMedica Superspecialty Hospital ,127, Mukundapur E.M. Bypass Kolkata (India) - 700099 India ECR/202/Inst/WB/2013/RR-19
5.	Dr Tukaram Jamale, Central Clinical Biochemistry Laboratory, Ward 34 A, third floor, old building, Department of Nephrology, Seth G.S Medical College and K.E.M Hospital, Parel Mumbai Mumbai City Maharashtra - 400012	Institutional Ethics Committee-I, Seth GS Medical College and KEM Hospital, Mumbai. Acharya Donde Marg, Parel, Mumbai, Mumbai City Maharashtra -400012 India ECR/229/Inst/MH/2013/RR-19
6.	Dr Santosh Varghese, 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 Vellore ECR/326/Inst/TN/2013/RR-19
7	Dr Bharat Vallabhdas Shah, Metropolis Healthcare Ltd CDKD Global Hospital Unit, 35, Dr. E Borges Road, Hospital Avenue Opp Shirodkar High School, Parel Mumbai Mumbai City Maharashtra – 400012.	Institutional Ethics Committee, Global Hospitals Global Hospitals, Mumbai Room No. 501, 5th floor, Dr. E. Borges Road, Hospital Avenue, Opp. Shirodkar High School, Parel Mumbai Mumbai City Maharashtra - 400012 India. ECR/493/Inst/MH/2014/RR-19
8	Dr Shivendra Singh, CCI LAB, S.S. Hospital, IMS, BHU Renal Lab, Department of Nephrology Varanasi Varanasi Uttar Pradesh - 221005	Institutional Ethics Committee Institute of Medical Sciences Institute of Medical Sciences Banaras Hindu University Varanasi Uttar Pradesh - 221005 India. ECR/526/Inst/UP/2014/RR-20

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.

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

New Delhi
Date: .....

24 AUG 2022