



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/24/000020

To,

M/s. Eli Lilly and Company (India) Pvt. Ltd.,
Plot No. 92, Sector 32, Institutional Area,
Gurugram, Haryana (India) -122001.

Sir,

With reference to your application No. GCT/CT04/FF/2024/41784 dated 06-02-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Effect of Lepodisiran on the Reduction of Major Adverse Cardiovascular Events in Adults with Elevated Lipoprotein(a) who have Established Atherosclerotic Cardiovascular Disease or Are at Risk for a First Cardiovascular Event –ACCLAIM-Lp(a)” Protocol No.: J3L-MC-EZEF Version No. Initial Protocol Date 17-DEC-2023 with a total of up-to 150 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) **KFT assessment including GFR and UTI test at 3 months shall be included in inclusion criteria. Accordingly, CKD patients should also be included, if full fill the said criteria;**
- (ii) **Patient diagnosed with low GFR undergoing any form of haemodialysis should be excluded from study;**
- (iii) **Human biological samples i.e. whole blood, serum, plasma and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (iv) **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;**
- (v) **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;

- (vi)** 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;
- (vii)** 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;
- (viii)** 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;
- (ix)** 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;
- (x)** 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;
- (xi)** 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;
- (xii)** 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;
- (xiii)** 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;
- (xiv)** 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;
- (xv)** 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;
- (xvi)** 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;
- (xvii)** 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;
- (xviii)** 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;
- (xix)** the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the

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objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

- (xx) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xxi) 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;
- (xxii) 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,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

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

1. The Central Licensing Authority hereby permits **M/s Eli Lilly And Company, Sector 32, Plot No. 92 Gurgaon Gurgaon (India) -122001 Telephone No.: 1244753000 FAX: 1244753012 E-Mail : IN_REG@LISTS.LILLY.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: J3L-MC-EZEF Version No. Initial Protocol Date 17-DEC-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	Iepodisiran sodium (LY3819469)
Therapeutic class:	RNA oligonucleotide
Dosage form:	Solution for injection
Composition:	LY3819469 Sodium =200.0000 mg/ml In House Specification Active Sodium Hydroxide =1.0000 mg/ml U.S.P. Inactive Hydrochloric Acid =1.0000 mg/ml U.S.P. Inactive
Indications:	Cardiovascular Disease

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Lisie Hospital, Cochin Kerala -682018	Institutional Ethics Committee, Lisie Hospita I, P.B No. 3053, Kochi, Kerala, India, 682018. ECR/40/Inst/KL/2013/RR-20	Dr Jabir Abdullakutty
King George's Medical College, Institutional Ethics Committee, King George's Medical College, Office of Research Cell, Administrative Block, KingGeorge's Medical University, Lucknow Uttar Pradesh - 226003	Institutional Ethics Committee, King George's Medical University, Office of the Research Cell, Sha h Mina Road, Lucknow, Uttar Pradesh, India , 226003 ECR/262/Inst/UP/2013 /RR-19	Dr S K Dwivedi
Govt. Medical College, Govt. Medical College, Kozhikode, 4thFloor, Golden jubilee Annex, Institute of Maternal and Child Health, Calicut Kerala - 673008	Institutional Ethics Committee, Government Medical College, Kozhikode, Room No.1 and 2, Ground Floor, Lecture Theatre Complex, Medical College Campus, Medical College P.O., Kozhikode, Kerala , India , 673008 ECR/395/Inst/KL/2013/RR-20	Dr Neeraj Manikath
Vijan Cardiac and Critical Care Centre, Vijan Cardiac and Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik Maharashtra - 422005	Vijan Hospital Ethics Committee, Vijan Cardiacand Critical Care Centre, Dr Vijan Hospital Marg, College Road, Nashik, Ma ha ra shtra, India , 422005 ECR/406/Inst/MH/2013/RR-19	Dr Vikrant Vijan
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	Institutional Ethics Committee, AIIMS Raipur, Room No. 2103, 2 nd Floor South Wing Medica I College Complex, Gate No. 5, All India Institute of Medical Sciences, Great Eastern Road, Ta tiba ndh, Raipur, Chhattisgarh, India , 492099 ECR/714/Inst/CT/2015/RR-21	Dr Satyajit Singh

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KCare Multispecialty Hospital, Civil Lines, Mall Road Kanpur Uttar Pradesh - 208001	Ethics Committee Brij Medical Centre, Brij Medical Center Pvt Ltd, Panki, Kanpur, Uttar Pradesh, India, 208020 ECR/642/Inst/UP/2014/RR-20	Dr Amit Kumar Gupta
Shri Mahant IndiresH Hospital, Kargi - Patel Nagar Bypass, Industrial Area, Govt.Industrial Estate, Patel Nagar Dehradun Uttarakhand - 248001	Institutional Ethics Committee, Shri Guru Ram Rai Institute of Medical & Health Sciences, Administrative Block, Patel Nagar, Dehradun, Uttarakhand, India , 248001 ECR/710/Inst/UK/2015/RR-21	Dr Tanuj Bhatia
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, NH 4A, Nehru Nagar, Belagavi, India, Karnataka Karnataka - 590010	Institutional Ethics Committee of KLE Academy of Higher Education and Research, J.N. Medical College Campus, Nehru Nagar, Belagavi, Karnataka, India, 590010 ECR/211/Inst/KA/2013/RR-19	Dr Prasad MR
G.B. Pant Institute of Postgraduate Medical Education and Research, Room No-133, First Floor, Academic Block, Department of Cardiology, Jawahar Lal Nehru Marg Delhi Delhi - 110002	Institutional Ethics Committee, Maulana Azad Medical College, Room No. 306-A, New Delhi, Delhi, India , 110002 ECR/329/Inst/DL/2013/RR-19	Dr Vimal Mehta
Sardar Patel Medical College and A. G. Hospitals, Research Cell-B-Block, Ground Floor, Haldiram Moolchand Wing Bikaner Rajasthan - 334003	Ethics Committee, S. P. Medical College, Pawanpuri, Bikaner, Rajasthan, India, 334003 ECR/27/SP/Inst/RJ/2013/RR-19	Dr Devendra K Agarwal
