



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/24/000130

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/2024/46079 dated 05-Nov-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **Phase III** clinical trial titled, "**A Master Protocol to Investigate the Efficacy and Safety of Orforglipron Once Daily in Participants Who Have Obstructive Sleep Apnea and Obesity or Overweight: A Randomized, Double-Blind, Placebo-Controlled Trial (ATTAIN-OSA)**" Protocol No.: **J5P-MC-GZRA** dated **08 Aug 2024** with a **total of up-to 50 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) **India specific addendum with respect to fundus examination at beginning midway and end shall be submitted.**
- (ii) **Human biological samples i.e. Whole blood, Serum and Plasma related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
- (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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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.

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 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.: J5P-MC-GZRA dated 08 Aug 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 _____

(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	LY3502970
	LY3502970
	LY3502970
	LY3502970
	LY3502970
	LY3502970
Therapeutic class:	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
Dosage form:	Capsules
	Capsules

	Capsules
	Capsules
	Capsules
	Capsules
Composition:	LY3502970 =3.3330 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
	LY3502970 =10.0000 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
	LY3502970 =20.0000 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
	LY3502970 =40.0000 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
	LY3502970 =80.0000 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
	LY3502970 =120.0000 milligram (mg) In House Specification Active Sodium Bicarbonate with 1% Dimethicone = 606.1000 milligram (mg) U.S.P. Inactive
Indications:	Obstructive Sleep Apnea and Obesity or Overweight
	Obstructive Sleep Apnea and Obesity or Overweight
	Obstructive Sleep Apnea and Obesity or Overweight
	Obstructive Sleep Apnea and Obesity or Overweight
	Obstructive Sleep Apnea and Obesity or Overweight
	Obstructive Sleep Apnea and Obesity or Overweight

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	All India Institute of Medical Sciences Department of Pulmonary, Sleep & Critical Care, Great Eastern Road, AIIMS Campus, Tatibandh, 1st floor, D block, Pulmonary Medicine, Gate No.4, AIIMS Raipur, G.E Road, Tatibandh, Raipur, Chhattisgarh, India, 492099	Institutional Ethics Committee, AIIMS Raipur, 2103 2nd Floor South Wing Medical College Complex, Gate No. 5 All India Institute of Medical Science Tatibandh, G.E Road, Raipur-492009, Chattisgrah India ECR/714/Inst/CT/2015/RR-21	Dr. Dibakar Sahu

2.	Sir Ganga Ram Hospital Sleep Medicine, Rajinder Nagar, 1st Floor, New Delhi, Delhi, India, 110060	Sir Ganga Ram Hospital Ethics Committee, 1643, 6th Floor, Casualty Building, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi - 110060 ECR/20/Inst/DL/2013/RR-24	Dr. Sanjay Manchanda
3.	Endolife Speciality Hospital No. 12-12-94 Old Club Road, 1 st Floor, Guntur, Andhra Pradesh, India, 522001	Institutional Ethics Committee of Endolife Hospitals No. 12-12-94 Old Club Road, Kothapet, Guntur- 522001, Andhra Pradesh, India ECR/647/Inst/AP/2014/RR-17	Dr. Gaddipati Rao Babu Rao
4.	SDS Tuberculosis Research Center & Rajiv Gandhi Institute of Chest Diseases, 1st Main Road, 1st Floor, Mon - Fri: 10:00 AM- 04:00PM, Bengaluru, Karnataka, India, 560029	Ethics Committee of SDS TRC and RGICD 1st Floor Administrative Block 1st Main Someshwara Nagar DC Post, Near NIMHANS Campus Bengaluru Karnataka – 560029 ECR/1700/Inst/KA/2022	Dr. Akshata J S
5.	All India Institute of Medical Sciences Ansari Nagar, New Delhi, Delhi, India, 110029	Ethics Committee AIIMS, Institute Ethics Committee, Room No. 102, First Old OT Block, AIIMS, Ansari Nagar New Delhi – 110029 ECR/538/Inst/DL/2014/RR-20	Dr. Saurabh Mittal
6.	Bhakti Vedanta Hospital and Research Institute, Bhaktivedanta Swami Marg, Mira Road, Bhaktivedanta Hospital & Research Institute, Opposite to ISKCON Temple, Thane, Maharashtra, India, 401107	Bhaktivedanta Hospital Ethics Committee, Bhaktivedanta Hospital and Research Institute Srishti Complex, Bhaktivedanta Swami Marg Mira Road (E) Thane Thane Maharashtra, 401107 ECR/396/Inst/MH/2023/RR-19	Dr. Ajay Madhav Godse
7.	Sleep & Snoring Clinic & Research Centre, Central Park Road, Nagpur, Maharashtra India, 440012	Crescent Hospital Institutional Ethics Committee, 3rd floor, Crescent Hospital Near Lokmat Square, DHantoli Nagpur-12 ECR/682/Inst/MH /2014/RR-12	Dr. Sushant Hiranman Meshram
8.	Villoo Poonawalla Memorial Hospital, Soli Poonawalla Road, B 13 Research Room, S.no 156, Hadapsar, Pune Maharashtra India, 411028	Institutional Ethics Committee of WMG's Villoo Poonawalla Memorial Hospital, WMF's Villoo Poonawalla Memorial Hospital, S.no. 156, Pune-Solapur Road, Haelopsar, Pune-411028, India ECR/1642/Inst/MH/2022	Dr. Nana Gokul Kunjir
9.	All India Institute of Medical Sciences – Rishikesh, Department of Pulmonary Medicine, Virbhadrha Road, Near Barrage, Rishikesh, Uttarakhand, India, 249203	Ethics Committee Relating to Clinical Trials, All India Institute of Medical Sciences Rishikesh, Virbhadrha Marg, Pashulok, Rishikesh, Dehradun, Uttarakhand -249203 India	Dr. Lokesh Kumar Saini

		ECR/736/Inst/UK/2015/RR-21	
10.	St. Johns Medical College Hospital, III floor, Unit of hope, Sarjaupur road, S.J.M.C.H., Bengaluru, Karnataka, India, 560034	Institutional Ethics Committee Ground Floor, St Johns Medical College Sarjapura Road, Bangalore, 560034 ECR/238/Inst/KA/2013/RR-24	Dr. George Albert D'Souza
