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/25/000051

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/2025/49349 dated 09-May-2025, 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 Tablet Once Daily Compared with Placebo in Participants with Obesity or Overweight with and without Type 2 Diabetes" Protocol No. J2A-MC-GZPO version no. initial dated 21 March 2025 with a total of up-to 130 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) **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. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xix) 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;

(xx) 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,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.09.26 10:15:18 +05'30'

(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 (India) Pvt. Ltd, Plot No. 92, Sector 32, Institutional Area, Gurugram, Haryana (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. J2A-MC-GZPO version no. initial dated 21 March 2025** 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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.09.26 10:15:29 +05'30'

(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:	GLP 1 receptor agonist
	GLP 1 receptor agonist
	GLP 1 receptor agonist
	GLP 1 receptor agonist
	GLP 1 receptor agonist
	GLP 1 receptor agonist
Dosage form:	Tablets
	Tablets
	Tablets

	Tablets
	Tablets
	Tablets
Composition:	LY3502970 =2.6670 milligram (mg) In House Specification Active Microcrystalline Cellulose=66.6100 milligram (mg) U.S.P. Inactive Crospovidone =8.5000 milligram (mg) U.S.P. Inactive Sodium Carbonate Anhydrous=6.8000 milligram (mg) U.S.P. Inactive Magnesium Stearate =0.4250 milligram (mg) U.S.P. Inactive
	LY3502970 =8.3330 milligram (mg) In House Specification Active Sodium Carbonate Anhydrous=6.8000 milligram (mg) U.S.P. Inactive Crospovidone =8.5000 milligram (mg) U.S.P. Inactive Microcrystalline Cellulose=60.9400 milligram (mg) U.S.P. Inactive Magnesium Stearate =0.4250 milligram (mg) U.S.P. Inactive
	Microcrystalline Cellulose=51.7100 milligram (mg) U.S.P. Inactive Crospovidone =15.9800 milligram (mg) U.S.P. Inactive Sodium Carbonate Anhydrous=7.5210 milligram (mg) U.S.P. Inactive Magnesium Stearate =0.4700 milligram (mg) U.S.P. Inactive LY3502970 =18.3300 milligram (mg) In House Specification Active
	LY3502970 =30.0000 milligram (mg) In House Specification Active Magnesium Stearate =0.7690 milligram (mg) U.S.P. Inactive Crospovidone =26.1500 milligram (mg) U.S.P. Inactive Sodium Carbonate Anhydrous=12.3100 milligram (mg) U.S.P. Inactive Microcrystalline Cellulose=84.6200 milligram (mg) U.S.P. Inactive
	Sodium Carbonate Anhydrous=19.8300 milligram (mg) U.S.P. Inactive Magnesium Stearate =1.2390 milligram (mg) U.S.P. Inactive LY3502970 =48.3300 milligram (mg) In House Specification Active Microcrystalline Cellulose=136.3000 milligram (mg) U.S.P. Inactive Crospovidone =42.1400 milligram (mg) U.S.P. Inactive
	Magnesium Stearate =1.4700 milligram (mg) U.S.P. Inactive Microcrystalline Cellulose=161.7000 milligram (mg) U.S.P. Inactive Crospovidone =49.9800 milligram (mg) U.S.P. Inactive Sodium Carbonate Anhydrous=23.5200 milligram (mg) U.S.P. Inactive LY3502970 =57.3300 milligram (mg) In House Specification Active
Indications:	Obesity or Overweight with and without Type 2 Diabetes
	Obesity or Overweight with and without Type 2 Diabetes
	Obesity or Overweight with and without Type 2 Diabetes
	Obesity or Overweight with and without Type 2 Diabetes
	Obesity or Overweight with and without Type 2 Diabetes
	Obesity or Overweight with and without Type 2 Diabetes

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 Ethics Committee, Room No 1496. IV Floor , Old Building ,Old Rajinder Nagar New Delhi Delhi - 110060	Sir Ganga Ram Hospital Ethics Committee, Room No 1643, 6th Floor, Casualty Building, Rajinder Nagar, New Delhi-110060, India ECR/20/INST/DL/2013/RR-24	Dr Ajay Aggarwal

2.	Ethics Committee, Chellaram Diabetes Institute, Ethics Committee, Chellaram Diabetes Institute, Lalani Quantum, Pune-Bangalore Highway, Bavdhan Budruk Pune Maharashtra - 411021	Chellaram Diabetes Institute-Institutional Ethics Committee, Chellaram Diabetes Institute, 1st floor, Lalani Quantum, Pune-Bangalore NH- 4, Bavdhan (Budruk), Pune-411021, Maharashtra, India ECR/203/Inst/MH/2014/RR-20	Dr Unnikrishnan Ambika
3.	All India Institute of Medical Sciences , Ethics Committee All India Institute of Medical Sciences situated at Village Sijua, Patrapada, PO Dumduma, Bhubaneshwar Orissa - 751019	Institute Ethics Committee (Human Studies) - AIIMS, Bhubaneshwar, Sijua, Patrapada, Bhubaneswar, Odisha 751019, India ECR/534/Inst/OD/2014/RR-25	Dr Kishore Kumar Behera
4.	Institute All India Institute of Medical Sciences,, Institute Ethics Committee, AllIndia Institute of Medical Sciences, Department of Physiology, Veerbhadra Marg, Rishikesh Uttarakhand -249201	Institutional Ethics Committee, AIIMS Rishikesh, All India Institute of Medical Sciences, Rishikesh, Virbhadra Marg, Pashulok, Rishikesh, Dehradun, Uttarakhand – 249203, India ECR/736/Inst/UK/2015/RR-21	Dr Kalyani Sridharan
5.	Diabetes Research Center, 6 3349 17B 31, Hindi Nagar Colony, Behind Panjagutta Saibaba Temple, Penjagatta hyderabad Telangana - 500082	Institutional Ethics Committee, Diabetes Research Center, First Floor 6-3-349/17B, Hindi Nagar Colony, Behind Panjagutta Saibaba Temple, Hyderabad, Telangana - 500082 India ECR/1955/Inst/TG/2024,15-Apr-2024	Dr Paturi Vishnupriya Rao
6.	Apollo Excelcare Hospital, Apollo Excelcare Hospital Guwahati, Paschim Boragaon, Near Ganesh Mandir uwahati Assam - 781033	Institutional Ethics Committee, Apollo Excelcare Hospital Guwahati, Paschim Boragaon, Near Ganesh Mandir, Guwahati 781033, Assam ECR/1230/Inst/AS/2019/RR-22	Dr Manash Pratim Baruah
7.	Karnataka Medical College and Research Institute, Hubballi, PB Road, Vidyanagar, Hubli Hubbbali Karnataka - 580021	KMCRI ETHICS COMMITTEE, Karnataka Medical College And Research Institute Office of the Principal Vidyanagar HUBBALLI Dharwad Karnataka - 580021 India ECR/486/Inst/KA/2013/RR-25	Dr Ram S Kaulgud

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