**File No. CT/39/24-DCG(I)**


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


सत्यमेव जयते

**File No. CT/24/000039**

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/2024/42284 dated 08-03-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Event-Driven Study to Investigate the Effect of Retatrutide (LY3437943) on the Incidence of Major Adverse Cardiovascular Events and the Decline in Kidney Function in Participants with Body Mass Index ≥27 kg/m2 and Atherosclerotic Cardiovascular Disease and/or Chronic Kidney Disease(TRIUMPH-OUTCOMES)" Protocol No.: J1I-MC-GZBO Version No. a Protocol Date 05-JAN-2024 with a total of up-to 530 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) The PI should be cardiologist, and Co-PI should be nephrologist.**

**(ii) 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.**

**(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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bb5a263a4a73d625f4b11b680a91f08773480400a43ee361b, postalCode=110002, st=Delhi, serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.10.01 12:14:07 +05'30'

Yours faithfully,

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

**File No. CT/39/24-DCG(I)**

**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.: J1I-MC-GZBO Version No. a Protocol Date 05-JAN-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 _____

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bb5a263a4a73d025ff4b11b680a9f08773480400a43ee361b, postalCode=110002, st=Delhi, serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
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(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** | Retatrutide |
| | Retatrutide |
| | Retatrutide |
| | Retatrutide |
| | Retatrutide |
| **Therapeutic class:** | GIP GLP1 glucagon receptor triagonist |
| | GIP GLP1 glucagon receptor triagonist |
| | GIP GLP1 glucagon receptor triagonist |
| | GIP GLP1 glucagon receptor triagonist |
| | GIP GLP1 glucagon receptor triagonist |
| **Dosage form:** | Solution for injection |
| | Solution for injection |
| | Solution for injection |
| | Solution for injection |
| | Solution for injection |

| | |
|---|---|
| **Composition:** | LY3437943 =900.0000 mg/ml In House Specification Active<br>Tris(hydroxymethyl)aminomethane =90.8000 mg/ml U.S.P. Inactive<br>Mannitol =3600.0000 gram (g) U.S.P. Inactive |
| | LY3437943 =150.0000 mg/ml In House Specification Active<br>Tris(hydroxymethyl)aminomethane =90.8000 gram (g) U.S.P. Inactive<br>Mannitol =3600.0000 gram (g) U.S.P. Inactive |
| | LY3437943 =300.0000 mg/ml In House Specification Active<br>Tris(hydroxymethyl)aminomethane =90.8000 gram (g) U.S.P. Inactive<br>Mannitol =3600.0000 gram (g)U.S.P. Inactive |
| | LY3437943 =400.0000 mg/ml In House Specification Active<br>Tris(hydroxymethyl)aminomethane =90.8000 gram (g) U.S.P. Inactive<br>Mannitol =3600.0000 gram (g) U.S.P. Inactive |
| | LY3437943 =700.0000 mg/ml In House Specification Active<br>Tris(hydroxymethyl)aminomethane =90.8000 gram (g) U.S.P. Inactive<br>Mannitol =3600.0000 gram (g) U.S.P. Inactive |
| **Indications:** | Cardiovascular Disease and/or Chronic Kidney Disease |
| | Cardiovascular Disease and/or Chronic Kidney Disease |
| | Cardiovascular Disease and/or Chronic Kidney Disease |
| | Cardiovascular Disease and/or Chronic Kidney Disease |
| | Cardiovascular Disease and/or Chronic Kidney Disease |

**Annexure:**

Details of clinical trial site:

| Sr. No. | Names and address of clinical trial site | Ethics committee details | Name of investigator |
|---|---|---|---|
| **1.** | Manipal Hospitals<br>No. 85-86, Bangalore-Mysore Ring Road, Bannimantapa 'A' Layout, Siddique Nagar, Mysore - 570015, Karnataka, India | Institutional Ethics Committee Columbia Asia Hospital Mysore, No. 85-86, Bangalore-Mysore Ring Road, Bannimantapa 'A' Layout, Siddique Nagar, Mysore - 570015, Karnataka, India<br><br>ECR/1106/Inst/KA/2018/RR-21 | Dr Chakrabhavi Basavegowda Keshavamurthy |
| **2.** | S C B Medical College and Hospital Behera Colony, Cuttack, Odisha, India, 753001 Ring road, Surat, Gujarat, India 395002 | Institutional Ethics Committee, SCB Medical College and Hospital, Cuttack -753007, Odisha, India<br><br>ECR/390/Inst/GJ/2013/RR-19 | Dr Dipak Ranjan Das |

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| **3.** | Nirmal Hospital Private Limited Ring road, Surat, Gujarat, India 395002 | Nirmal Hospital Ethics Committee, Nirmal Hospital Private Limited, 2/1423-8-6, Sagrampura, Ring road, Near Centre Point, Surat-395002, Gujarat, India<br><br>ECR/390/Inst/GJ/2013/RR-19 | Dr Pritesh Parekh |
| **4.** | Government Medical College –Kozhikode Calicut, Kozhikode, Kerala, India, 673008 | Institutional Ethics Committee, Government Medical College, Kozhikode, Room No. 1 and 2, Ground Floor, Lecture Theatre Complex, Medical College Campus, Medical College P.0, Calicut, Kozhikode - 673008, Kerala, India.<br><br>ECR/395/Inst/KL/2013/RR-20 | Dr Neeraj Manikath |
| **5.** | All India Institute of Medical Sciences Sijua, G-Block, Department of Trauma Emergency Cardiology OPD, Bhubaneswar, Odisha, India, 751019 | Institutional Ethics Committee, AIIMS, Bhubaneswar, Sijua, Dumduma, Patrapada, Bhubaneswar, Odisha, India, 751019<br><br>ECR/534/Inst/OD/2014/RR-20 | Dr Saroj Kumar Sahoo |
| **6.** | All India Institute of Medical Sciences Dept. of Nephrology, Ansari Nagar,Delhi, India, 110029 | Institutional Ethics Committee, Room No.102, 1st Floor, old OT Block, AIIMS, Ansari Nagar, Delhi, India, 110029<br><br>ECR/538/Inst/DL/2014/RR-20 | Dr Soumita Bagchi |
| **7.** | All India Institute of Medical Sciences – Raipur Eastern Road, AIIMS Campus, Tatibandh, Raipur -492099, Chhattisgarh, India | Institutional Ethics Committee, AIIMS, Raipur, Room No. 2103, 2nd Floor, South Wing Medical College Complex, Gate No. 5, Great Eastern Road, AIIMS Campus, Tatibandh, Raipur - 492099, Chhattisgarh, India<br><br>ECR/714/Inst/CT/2015/RR-21 | Dr Vinay Rathore |
| **8.** | Shri B. D. Mehta Mahavir Heart Institute Shri B.D. Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Athwa gate, Ring Road, OPD area, Surat, Gujarat, India, 395001 | Shri B. D. Mehta Mahavir Heart Institute Ethics Committee, Shree Mahavir Health Campus, Opp. Vanita Vishram Ground Athwagate, Ring Road, Surat, Gujarat - 395001 India<br><br>ECR/850/Inst/GJ/2016/RR-20 | Dr Atul Damodar Abhyankar |

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| **9.** | Dr. Ram Manohar Lohia Institute of Medical Sciences Vibhuti Khand, Gomti Nagar, Lucknow, Uttar Pradesh, India, 226010 | Institutional Ethics Committee, Research Cell Office, Room No. 35, 2nd Floor, Administrative Block, Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow, Uttar Pradesh -226010 India<br><br>ECR/913/Inst/UP/2017/RR-20 | Dr Naveen Jamwal |
| **10.** | Life Care Hospital and Research Centre 2748/2152 M.L.N Enclave, 16th E Cross Road, 8thMain, D block, Sahakarnagar, Bengalaru, 560092, India | Lifecare Hospital Institutional Review Board, 2748/2152 M.L.N Enclave, 16th E Cross Road, 8thMain, D block, next to Union Bank of India, Sahakarnagar, Bengalaru, 560092, India<br><br>ECR/883/Inst/KA/2017/RR-20 | Dr Prasad Mahabaleshwar Bhat |
| **11.** | LPS Institute of Cardiology GT Road, Kanpur, Uttar Pradesh, India, 208002 | Ethics Committee GSVM Medical College Kanpur, Room No 125, 1st Floor, GSVM Medical College Kanpur, 208002, UP, India<br><br>ECR/680/Inst/UP/2014/RR-20 | Dr Awadhesh Kumar Sharma |
| **12.** | G.B. Pant Institute of Postgraduate Medical Education & Research Room No-133, First Floor, Academic Block, Department of Cardiology, Jawahar Lal Nehru Marg, New Delhi, Delhi, India, 110002 | Institutional Ethics Committee, Room No-306-A, Maulana Azad Medical College, New Delhi, India, 110002<br><br>ECR/329/Inst/DL/2013/RR-19 | Dr Vimal Mehta |
| **13.** | Shri Mahant Indiresh Hospital Shri Guru Ram Rai Institute of Medical & Health Sciences, Patel Nagar, 4th Floor, Patel Nagar, Dehradun, Uttarakhand, India, 248001 | Institutional Ethics Committee, Administrative Block, Ground Floor, Shri Guru Ram Rai Institute of Medical and Health Sciences, Patel Nagar, Dehradun,-248001, Uttarakhand, India<br><br>ECR/710/Inst/UK/2015/RR-21 | Dr Vivek Ruhela |
| **14.** | Sir Ganga Ram Hospital Rajinder Nagar, Nephrology Research, Room No 1297, 2nd Floor, Old Rajinder Nagar, New Delhi, Delhi, India, 110060 | Ethics Committee, Sir Ganga Ram Hospital, Old Rajinder Nagar, 5th Floor, Academic area, New Delhi, Delhi, India, 110060<br><br>ECR/20/Inst/DL/2013/RR-19 | Dr Anil Kumar Bhalla |

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| **15.** | K Care Hospital 16, Civil Lines Road, Kanpur, Uttar Pradesh, India, 208001 | Ethics Committee Brij Medical Centre Private Limited, Panki Kanpur, Nagar Kanpur, Utar Pradesh-208020, India<br><br>ECR/642/Inst/UP/2014/RR-20 | Dr Amit Kumar Gupta |
| **16.** | Medway Heart Institute 2/26, 1st Main Road, Medway Heart Institute basement, Chennai, Tamil Nadu, India, 600024 | Institutional Ethics Committee - Medway Hospitals, 2/26, 1st Main Road, United India Colony, Kodambakkam, Chennai, Tamil Nadu, India, 600024<br><br>ECR/1788/Inst/TN/2023 | Dr Jai Shankar Krishnamoorthy |
| **17.** | All India Institute of Medical Sciences (AIIMS) –Nagpur Plot 2,Sector 20 Mihan, Nagpur, Maharashtra, India, 441108 | All India Institute of Medical Sciences, Nagpur,M/S Director AIIMS, Plot No 2, Sector 20 1stFloor, OPD Building, MIHAN, Nagpur, Maharashtra–441108, India<br><br>ECR/1392/Inst/MH/2020 | Dr Amol Bhawane |
| **18.** | Motilal Nehru Medical College Hospital George Town Civil Lines,Prayagraj, Allahabad, Uttar Pradesh, India, 211002 | Institutional Ethics Committee MLN Medical College, Motilal Nehru Medical College Hospital, George Town, Prayagraj, Allahabad, Uttar Pradesh, India, 211002<br><br>ECR/955/Inst/UP/2017/RR-22 | Dr Santosh Kumar Maurya |
| **19.** | Shrikrishna Hrudayalaya And Critical Care Center Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur - 440012, Maharashtra, India | Virtuous Institutional Medical Research Ethics Committee, IV Floor, Shrikrishna Hrudayalaya and Critical Care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur 440012, Maharashtra, India<br><br>ECR/548/Inst/MH/2014/RR-20 | Dr Mahesh Chandumal Fulwani |
| **20.** | KIMS Kingsway Hospitals 44 Kingsway, Parwana Bhawan, Nagpur, 440001, Maharashtra, India | Kingsway Hospitals Ethics Committee, Kingsway Hospitals 44, Parwana Bhawan, Nagpur, 440001, Maharashtra, India<br><br>ECR/1269/Inst/MH/2019 | Dr Rishi Vinod Lohiya |

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