



सत्यमेव जयते

GOVERNMENT OF INDIA  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION (Headquarter)  
(Directorate General of Health  
Services) Ministry of Health & Family  
Welfare  
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**File No. CT/25/000015**

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/2025/47870 dated 14-Feb-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3, Multicenter, Double-Blind, Placebo-controlled Study Assessing the Efficacy and Safety of Olomorasib in Combination with Standard of Care Immunotherapy in Participants with Resected or Unresectable KRAS G12C-Mutant, Non-Small Cell Lung Cancer -SUNRAY-02”** Protocol No.: J3M-MC-JZQH version no. Initial protocol dated 13-NOV-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) **More geographically distributed government sites shall be included in the study.**
- (ii) **PI shall be Medical Oncologist only.**
- (iii) **Number of subjects shall be increased upto 50.**
- (iv) **Human biological samples i.e. Whole blood, Serum, Plasma, Urine and Tumor tissue 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.**
- (v) 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;
- (vi) 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;

- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) 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;
- (xix) 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;
- (xx) 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;
- (xxi) the sponsor and the investigator shall maintain the data integrity of the data generated

during clinical trial.

- (xxii) 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;
- (xxiii) 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.: J3M-MC-JZQH version no. Initial protocol dated 13-NOV-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

**Annexure:**

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug</b>	LY3537982
	LY3537982
<b>Therapeutic class:</b>	Anticancer
	Anticancer
<b>Dosage form:</b>	Capsules
	Capsules
<b>Composition:</b>	LY3537982 =25.0000 milligram (mg) In House Specification Active Microcrystalline Cellulose =92.5000 milligram (mg) U.S.P. Inactive
	LY3537982 =50.0000 milligram (mg) In House Specification Active Microcrystalline Cellulose =185.0000 milligram (mg) U.S.P. Inactive
<b>Indications:</b>	Resected or Unresectable KRAS G12C-Mutant, Non-Small Cell Lung Cancer
	Resected or Unresectable KRAS G12C-Mutant, Non-Small Cell Lung Cancer

**Annexure:**

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Malabar Cancer Centre Department of Clinical Hematology and Clinical Oncology, Malabar Cancer Centre, Post Graduate Institute of Oncology Science & Research, Moozhikkara PO, Kodyerum Thalassery, Kannur, Kerala India - 670103	Institutional Ethics Committee - Malabar Cancer Centre	Dr. Nandhini Devi R
2.	Thangam Cancer Center and Research Institute 54 Dr. Sankaran Road, Namakkal, Tamil Nadu, India, 637001	Thangam Hospital-Institutional Ethics Committee	Dr. Bhavesh Poladia
3.	Regional Cancer Centre College Campus, Trivandrum, Kerala- 695011	Human Ethics Committe	Dr. Anoop T M

4.	Deenanath Mangeshkar Hospital and Research Centre, Department of Research, 6th Floor C Wing, Deenanath Mangeshkar Hospital and Research Centre, Off Karve Road. Erandawane Pune Maharashtra - 411004	Institutional Ethics Committee Deenanath Mangeshkar Hospital & Research Centre Gulawani Maharaj Road, Erandwane, Pune, Maharashtra, India, 411004  ECR/15/Inst/Maha/2013/RR-22	Dr Chetan Dilip Deshmukh
5.	Mahamana Pandit Madan Mohan Malaviya Cancer Centre and Homi Bhabha Cancer Hospital, Varanasi, Uttar Pradesh, India, 221005 Varanasi Uttar Pradesh - 221005	Institutional Ethics Committee, MPMCC and HBCH (Unit of Tata Memorial Centre, Mumbai), Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi – 221005, Uttar Pradesh, India  ECR/1501/Inst/UP/2021	Dr Bipinesh Sansar
6.	Hemato Oncology Clinic Ahmedabad Pvt. Ltd, Nirmaya Complex, Ground Floor to Third Floor, Beside Pandit Dindayal Upadhyay Auditorium, Rajpath Club Road, Off S.G. Highway, Ahmedabad Ahmedabad Gujarat - 380054	Swarnim Ethics Committee Netralaya Super Speciality Eye Hospital, 1 <sup>st</sup> Floor, Kay Dee House, Opp. Gujarat Gas, Parimal Garden Cross Road, Ellisbridge, Ahmedabad-380006 Gujarat, India  ECR/1922/Inst/GJ/2024	Dr Chirag Jyotiker Desa
7.	Rajiv Gandhi Government General Hospital Madras Medical College, GH Post Office, Ponamalle High Road, 3 Grans Southern Trunk Road, Park Town, Nera Chennai Central, Chennai, Tamil Nadu-600004	Madras Medical College	Dr. Kannan Jayaraman
8.	Galaxy Superspeciality Hospital, Agnihotra Chowk, opp to Punjabi National Bank, Ulkanagari, Aurangabad Maharashtra Aurangabad Maharashtra - 431001	Ethics Committee of Ishwar Institute of Health Care	Dr. Ketan Shirsath
9.	Penta-Med, C/O, Medipoint Hospital Pvt. Ltd., New DP Road, Aundh, Pune Maharashtra - 411007	Penta-Med Ethics Committee Medipoint Hospitals Pvt. Ltd., 241/1 New D. P. Road, Near Sai Heritage, Aundh, Pune-411007, Maharashtra, India	Dr Rahul Suhas Kulkarni

		ECR/357/Inst/MH/2013/RR-20	
10.	Pacific Medical College and Hospital, Bhillo Ka Bedla Girwa Pratapura Udaipur, Rajasthan-313001, India Udaipur Rajasthan - 313001	Institutional Human Ethics Committee of PMCH Bhillo Ka Bedla, The Girwa Pratap Pura Udaipur, Rajasthan-313001, India  ECR/808/Inst/RJ/2017/RR-21	Dr Manoj Umeshchandra Mahajan
11.	Savera Cancer and Multispeciality Hospital, Lohiya Nagar, Near Rajendra Nagar Overbridge, Dr. R.N. Singh Road, Kankarbagh, Patna-800020 patna Bihar - 800020	Savera Cancer & Multispecialty Hospital-Institutional Ethics Committee Savera Cancer & Multispecialty Hospital, Lohiya Nagar, Near Rajendra Nagar Overbridge, Dr. R.N. Singh Road, Kankarbagh, Patna-800020  ECR/1658/Inst/BR/2022	Dr Avinash Pandey
12.	Sir H.N. Reliance Foundation Hospital and Research Centre, Prarthana Samaj, Raja Rammohan Roy Road, Girgaum Mumbai Maharashtra - 400004	IEC of Sir H N Reliance Foundation Hospital and Research Centre Prarthana Samaj, Raja Rammohan Roy Road, Girgaum Mumbai-400004  ECR/1389/Inst/MH/2020	Dr Sewanti Atul Limaye

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