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/24/000088

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/2024/44028 dated 01-JUL-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **Phase III** clinical trial titled, "**SUNRAY-01, A Global Pivotal Study in Participants with KRAS G12C-Mutant, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Comparing First-Line Treatment of LY3537982 and Pembrolizumab vs Placebo and Pembrolizumab in those with PD-L1 expression ≥ 50% or LY3537982 and Pembrolizumab, Pemetrexed, Platinum vs Placebo and Pembrolizumab, Pemetrexed, Platinum regardless of PD-L1 Expression" Protocol No.: J3M-MC-JZQB Version No. e Protocol Date 12-APR-2024 with a total of up-to 48 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) That PI shall be Medical Oncologist only.

(ii) Human biological samples i.e. Human blood (whole), Urine, Serum, Plasma and Tumor tissue 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.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(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-JZQB Version No. e Protocol Date 12-APR-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
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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	LY3537982 LY3537982
Therapeutic class:	Anticancer Anticancer
Dosage form:	Capsules Capsules
Composition:	LY3537982 =50.0000 milligram (mg) In House Specification Active Microcrystalline Cellulose=92.5000 milligram (mg) U.S.P. Inactive LY3537982 =100.0000 milligram (mg) In House Specification Active Microcrystalline Cellulose=185.0000 milligram (mg) U.S.P. Inactive

Indications:	Locally Advanced or Metastatic Non-Small Cell Lung Cancer
	Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Kolhapur Cancer Center, RS 238, Opp. Mayur Petrol Pump, Gokul Shirgaon, Kolhapur – 414234, Maharashtra, India	Institutional Ethics Committee Kolhapur Cancer Centre, RS 238, Opp Mayur Petrol Pump, Gokul Shirgaon, Kolhapur – 416234, Maharashtra, India ECR/523/Ins/MH/2014/RR-20	Dr. Nilesh Dhamne
2.	Regional Cancer Centre –Thiruvananthapuram, Kumarapuram Road, Thiruvananthapuram – 695011, Kerala, India	Human of Ethics Committee 1stFloor Regional Cancer Centre, Medical College Campus, Thiruvananthapuram –695011, Kerala, India ECR/21/Inst/Ker/2013/RR-19	Dr. Anoop Thattungal Manoharan
3.	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Department of Medical Oncology, NH 4A Nehru Nagar, Belgaum, Belagavi –590010, Karnataka, India	Institutional Ethics Committee of KLE Academy of Higher Education and Research JNMC Campus, KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belgaum, Belgavi –590010, Karnataka, India ECR/211/Inst/KA/2013/RR-24	Dr. Rohan Basawantrao Bhise
4.	Tata Memorial Hospital, Dr. Ernest Borges Marg Road, Parel, Mumbai – 400012, Maharashtra, India	Institutional Ethics Committee Office, Main Building, 3rdFloor, Dr. Ernest Borges Road, Tata Memorial Hospital, Parel, Mumbai –400012, Maharashtra, India IEC-1: ECR/170/Inst/MH/2013/RR-22 IEC-2: ECR/414/Inst/MH/2013/RR-19	Dr. Amit Joshi

5.	Rajiv Gandhi Cancer Institute and Research Centre, 18, Sir Chotu Ram Marg, Rohini Institutional Area, Sector 5, Rohini –110085, New Delhi, India	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Rohini Institutional Area, Sector 5, Rohini –110085, New Delhi, India ECR/10/Inst/DC/2013/RR-19	Dr. Mansi Sharma
6.	Grant Medical Foundation –Ruby Hall Clinic, 40 Sassoon Road, Pune – 411001, Maharashtra, India	Institutional Ethics Committee Poona Medical Research Foundation E4-C to E4-F, 4thFloor, 5th Avenue Condominium, Dhole Patil Road, Pune –411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-22	Dr.Minish Jain
7.	SRV Agadi Hospital and Research Centre, 35, Siddaiah Road, Wilson Garden, Bengaluru – 560027, Karnataka, India	Medstar Speciality Hospital Ethics Committee No. 641/17/1/3, 2ndFloor, Research Department, Medstar Speciality Hospital, Kodigehalli Main Road, Sahakarnagar, Bengaluru – 560094, Karnataka India ECR/1324/Inst/KA/2019	Dr. Lokesh KN
8.	Nizam's Institute of Medical Sciences (NIMS), Department of Medical Oncology, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad –500082, Telangana, India	NIMS-Institutional Ethics Committee (NIEC) 2nd Floor, SRC, Old Building, NIMS, Punjagutta, Hyderabad –500082, Telangana, India ECR/303/Inst/AP/2013/RR-19	Dr. Sadashivudu Gundeti
9.	All India Institute of Medical Sciences (AIIMS), Department of Medical Oncology and Hematology, Sijua P/O Patrapada, Khorda, Bhubaneswar –751019, Odisha, India	Institutional Ethics Committee AIIMS, Sijua P/O Patrapada, Khorda, Bhubaneswar – 751019, Odisha, India ECR/534/Inst/OD/2014/RR-20	Dr. Sourav Mishra
10.	Banaras Hindu University, Department of Radiotherapy and Radiation Medicine, Institute of Medical Sciences, Varanasi – 221005, Uttar Pradesh, India	Institutional Ethics Committee Institute of Medical Sciences, Banaras Hindu University, Varanasi –221005, Uttar Pradesh, India ECR/526/Inst/UP/2014/RR-20	Dr. Sunil Choudhary

11.	Krishna Vishwa Vidyapeeth (Deemed to be University), Bangalore Highway, Malkapur, Karad –415539, Maharashtra, India	Institutional Ethics Committee Krishna Institute of Medical Sciences (KIMS) Deemed to Be University, Bangalore Highway, Malkapur, Karad – 415539, Maharashtra, India ECR/307/Inst/MH/2013/RR-20	Dr. Rashmi Gudur
12.	Postgraduate Institute of Medical Education & Research (PGIMER), Department of Clinical Hematology and Medical Oncology, Sector 12 – 160012, Chandigarh, India	Institutional Ethics Committee (IEC) PGIMER, Room no. 6006, IEC Office, 6thFloor, PN Chuttani Block –160012, Chandigarh, India ECR/25/Inst/CH/2013/RR-20	Prof. Gaurav Prakash
13.	Jawaharlal Institute Of Postgraduate Medical Education And Research (JIPMER), Department of Medical Oncology, 3rdFloor, SSB, JIPMER Campus Road, Dhanvantri Nagar – 605006, Puducherry, India	Institutional Ethics Committee Intervention Studies 1stFloor, Admin Block, JIPMER, Dhanvantri Nagar – 605006, Puducherry, India ECR/342/Inst/PY/2013/RR-19	Dr.Prasanth Ganesan
14	HCG Manavata Cancer Centre, Department of Oncology and Hematology, Behind Shivang Auto, Mumbai Naka, Nashik –422002, Maharashtra, India	ManavataClinical Research Institute Ethics Committee HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik – 422002, Maharashtra, India ECR/500/Inst/MH/2013/RR-20	Dr. Rajnish Nagarkar
15.	Sahyadri Super Speciality Hospital, 30-C Karve Road, Erandwane, Pune –411004, Maharashtra, India	Sahyadri Hospitals Pvt. Ltd. Ethics Committee Sahyadri Clinical Research and Development Centre (A Unit of Sahyadri Hospitals Pvt. Ltd.), 33/34 Makrand Bhave Path, Erandwane, Pune – 411004, Maharashtra, India ECR/493/Inst/MH/2013/RR-19	Dr. Tushar Vishvasrao Patil
16.	Mahamana Pandit Madan Mohan Malaviya Cancer Centre (MPMMCC) and Homi Bhabha Cancer Hospital (HBCH) (Unit of Tata Memorial Centre, Mumbai), OPD No. 28,	Institutional Ethics Committee MPMMCC and HBCH (Unit of Tata Memorial Centre, Mumbai), Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi – 221005, Uttar Pradesh, India	Dr. Akhil Kapoor

	Department of Medical Oncology, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi –221005, Uttar Pradesh, India	ECR/1501/Inst/UP/2021	
17.	Ashwin Multispeciality Hospital, No. 1, Alamu Nagar, Sathy Main Road, Coimbatore –641012, Tamil Nadu, India	Institutional Ethics Committee Ashwin Multispeciality Hospital, No. 1, Alamu Nagar, Sathy Main Road, Coimbatore –641012, Tamil Nadu, India ECR/1795/Inst/TN/2023	Dr. Prabagar Manickam
18.	Mahatma Gandhi Cancer Hospital and Research Institute, 1/7 MVP Colony, Visakhapatnam –530017, Andhra Pradesh, India	Institutional Ethics Committee Mahatma Gandhi Cancer Hospital and Research Institute, 1/7 MVP Colony, Visakhapatnam –530017, Andhra Pradesh, India ECR/529/Inst/AP/2014/RR-20	Dr.Rajani Priya Yedla

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