



File No. BIO/CT/25/000139

Dated: 12-01-2026

To,
M/s Sun Pharmaceutical Industries Limited,
Tandalja Vadodara (India) – 390012

Subject: Application for grant of permission to conduct Phase III clinical trial entitled – “A Prospective, Multicenter, Randomized, Parallel Group, Double-Blind, Comparative, Active-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetic and Immunogenicity of Intravenous Infusion of Pembrolizumab (Sun Pharmaceutical Industries Limited) in comparison with Reference Medicinal Product (Keytruda) in treatment of Patients with Non-Squamous Metastatic Non-Small Cell Lung Carcinoma” vide Protocol No. ICR/25/012, Version No. 1.0; Dated 17/JUL/2025 - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2025/51788 dated 05.09.2025

Sir,

With reference to your application No BIO/CT04/FF/2025/51788 dated 05.09.2025, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (I) The sample size for the PK subset study shall be increased to 100 subjects.**
- (II) The DSMB report for the first 15 subjects shall be submitted to CDSCO for further evaluation by the SEC.**
- (III) Revised protocol incorporating above changes shall be submitted to CDSCO before initiation of clinical trial.**
- (IV) Clinical Study Report should be submitted to this office after completion of trial.
- (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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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) 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.
- (XIX) The Central Licensing 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.
- (XX) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XXI) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licensing Authority hereby permits M/s Sun Pharmaceutical Industries Limited, Tandalja Vadodara (India) - 390012 to conduct Phase III clinical trial titled- – “A Prospective, Multicenter, Randomized, Parallel Group, Double-Blind, Comparative, Active-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetic and Immunogenicity of Intravenous Infusion of Pembrolizumab (Sun Pharmaceutical Industries Limited) in comparison with Reference Medicinal Product (Keytruda) in treatment of Patients with Non-Squamous Metastatic Non-Small Cell Lung Carcinoma” vide Protocol No. ICR/25/012, Version No. 1.0; Dated 17/JUL/2025 in the below mentioned clinical trial sites.

2. Details of 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.
- 4. The sample size for the PK subset study shall be increased to 100 subjects.**
- 5. The DSMB report for the first 15 subjects shall be submitted to CDSCO for further evaluation by the SEC.**
- 6. Revised protocol incorporating above changes shall be submitted to CDSCO before initiation of clinical trial.**
7. It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 12 Jan 2026

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Pembrolizumab Injection 100 mg/4 mL (25 mg/mL) in a single vial (r-DNA origin)	
Therapeutic class	Anticancer	
Dosage form:	Solution in single -dose vial (For Intravenous infusion)	
Composition:	Each mL contains:	
	Name of Ingredients	Quantity per mL
	Pembrolizumab (Active Ingredient), In-house	25 mg
	L-Histidine USP	0.3 mg
	L-Histidine Hydrochloride Monohydrate Ph., Eur.	1.7 mg
	Polysorbate-80 IP	0.2 mg
	Sucrose IP	70 mg
	Water for injection IP, BP	q.s to 1mL
Indications:	Indicated for Non Squamous Metastatic Non Small Cell Lung Carcinoma	

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Mangalore Institute of Oncology Hospital, Pumpwell, Mangalore-575002, Karnataka.	Mangala Hospital And Mangala Kidney Foundation Vajra Hills Kadri Road Mangaluru Dakshina Kannada Karnataka -575003 India EC reg No. ECR/567/Inst/KA/2014/RR-24	Dr. Krishna Prasad
2.	Rajiv Gandhi Cancer Institute and Research Centre Sir Chotu Ram Marg, Rohini Institutional Area, Sector 5, Rohini Delhi - 110085	Ethics committee Rajiv Gandhi Cancer Institute and Research Centre Sir Chotu Ram Marg, Rohini Institutional Area, Sector 5, Rohini Delhi -110085 EC reg No. ECR/10/Inst/DC/2013/RR-24	Dr. Abhinav Dewan
3.	Jaipur National University Institute for Medical Sciences and Research Centre, Near New RTO Office, Agra Road, Jagatpura, Jaipur, Rajasthan, 302017	JNU Institute for Medical Sciences and Research Centre Jagatpura Jaipur Rajasthan -302017 India EC Reg No. ECR/905/Inst/RJ/2017/RR-25	Dr. Subhash Chand Bairwa

4.	Ground Floor, Department of Oncology, Aakash Healthcare Super Speciality Hospital, Hospital Plot, Road No. 201, Dwarka Sector-3, Dwarka, Delhi-110075	Aakash Healthcare Super Specialty Hospital, Hospital Plot, Road No. 201 Sector 3 Dwarka New Delhi Dwarka North West Delhi -110075 India EC Reg No. ECR/1265/Inst/DL/2019/RR-24	Dr.Parveen Jain
5.	Dr. B.L.Kapur Memorial Hospital Pusa Road, New Delhi-110005	Dr B L Kapur Memorial Hospital Academic Affairs Research And Continuing Education Pusa Raod Rajendra Place New Delhi -110005 India EC Reg No. ECR/3/BLK/Inst/DL/2013/RR-24	Dr. Chandragouda Dodagoudar
6.	Indraprastha Apollo Hospital, Sarita Vihar, Delhi Mathura Road, New Delhi-110076.	Indraprastha Apollo Hospital, Sarita Vihar, Delhi Mathura Road, New Delhi-110076 EC reg No. ECR/5/Inst/DL/2013/RR-24	Dr. Pratap Kishore Das
7.	Room no 26, Out Patient Block, Ground floor Department of Medical Oncology, Nizams Institute of Medical Sciences, Panjagutta, Hyderabad 500082 Telanagana	NIMS Institutional Ethics Committee, Nizams Institute of Medical Sciences Punjagutta Hyderabad Telangana -500082 India EC reg No. ECR/303/Inst/AP/2013/RR-24	Dr.GUNDETI SADASHIVUD U
8.	Department of Medical Oncology & BMT, RK Birla Cancer Center, JLN Marg, SMS Hospital, Jaipur, 302004	Ethics Committee S.M.S. Medical College and Attached Hospitals, JLN Marg, SMS Hospital, Jaipur, 302004 EC reg No. ECR/26/Inst/RJ/2013/RR-24	Dr. Jasuja Sandeep Kumar
9.	Vedant Multispeciality Hospital, ground floor, GP 83, Opp Rotary Club. Sambhaji Nagar, MIDC. Chinchwad, Pune-411019	IEC-Vedant Multispeciality Hospital Vedant Multispeciality Hospital Plot No .GP83, G-Block, MIDC, Sambhajinagar Chinchwad Pune Maharashtra -411019 India EC reg No. ECR/1426/Inst/MH/2020/RR-25	Dr. Wategaonkar Ravikumar Narayan
10.	Deenanath mangeshkar hospital and research Center, Ground floor, Oncology Department, Annex Building, Deenanath Mangeshkar hospital and research Center, Erandwane Pune-411004	Institutional Ethics committee Deenanath mangeshkar hospital and research Center, Ground floor, Oncology Department, Annex Building, Deenanath Mangeshkar hospital and research Center, Erandwane Pune-411004 EC reg No. ECR/15/Inst/Maha/2013/RR-22	Dr. Deshmukh Chetan Dilip
11.	State Cancer Institute, Department of Medical Oncology Indira Gandhi Institute of Medical Sciences, Indira Gandhi institute of Medical Sciences, Sheikhpura Patna-800014, Bihar, India	Institutional Ethics Committee, IGIMS, Sheikhpura Indira Gandhi Institute Of Medical Sciences Sheikhpura Raja Bazar Patna Patna Bihar -800014 India EC reg No.	Dr. Alok Ranjan

		ECR/640/Inst/BR/2014/RR-20	
12.	All India Institute of Medical Sciences(AIIMS) Rishikesh Department of Medical Oncology Hematology, Virbhadrha Road, Rishikesh, Dist-Dehradum- 249203.Uttarakhand, India	Ethics Committee relating to Clinical Trial All India Institute of Medical Sciences(AIIMS) Rishikesh Department of Medical Oncology Hematology, Virbhadrha Road, Rishikesh, Dist-Dehradum- 249203.Uttarakhand, India EC reg No. ECR/736/Inst/UK/2015/RR-21	Dr. Amit Sehrawat
13.	All India Institute of Medical Sciences Raipur. Department of Medical Oncology, Gate No.04 ,B-Block, Basement,Room No.01,G.E. Road, Tatibandh, Raipur - 492099 (C.G.	Institute Ethics Committee, AIIMS, Raipur, Room no. 2103, 2nd Floor South Wing Medical College Complex, Gate No. 5 All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, 492099, Chhattisgarh, India EC reg No. ECR/714/Inst/CT/2015/RR-21	Dr. Amit Kumar
14.	Acharya Harihar Post Graduate Institute of Cancer, Mangalabag, Cuttack, Odisha 753007	Institutional Ethics Committee, Acharya Harihar Post Graduate Institute of Cancer, Mangalabag, Cuttack, Odisha 753007 EC reg No. ECR/297/Inst/OR/2013/RR-24	Dr. Parida Prasant Kumar
15.	Department of Medical Oncology, Andhra Medical College, King George Hospital,Maharanipeta,Visakhapatnam-530002, Andhra Pradesh, India	IEC King George hospital, Department of Medical Oncology, Andhra Medical College, King George Hospital,Maharanipeta,Visakhapatnam-530002, Andhra Pradesh, India EC reg No. ECR/197/Inst/KGH/2013/RR-20	Dr. Shilpa Kandipalli
16.	Department of Oncology, Subharti Medical College &Hospital, Subhartipuram, NH-58, Delhi-Haridwar Bypass Road, Meerut-250005.UP.India	Subharti Medical College and Hospital, Department of Oncology, Subharti Medical College &Hospital, Subhartipuram, NH-58, Delhi-Haridwar Bypass Road, Meerut-250005.UP.India EC reg No. ECR/256/Inst/UP/2013/RR-24	Dr. Abhinav Narvariya
17.	Meenakshi Mission Hospital and Research Centre, Lake area, Melur road, Madurai. Tamil Nadu-625107	Institutional Ethics Committee, Meenakshi Mission Hospital and Research Centre, Lake area, Melur road, Madurai. Tamil Nadu-625107 EC reg No. ECR/398/Inst/TN/2013/RR-24	Dr. Krishna Kumar Rathnam

18.	K. R. Hospital, Mysore Medical College & Research Institute, Irwin Road, Mysuru-570001, Karnataka	IEC-MMC and RI and Associated Hospita, Mysore Medical College and Research Institutelrwin Road Mysuru Mysuru (Mysore) Karnataka -570001 India EC reg No. ECR/134/Inst/KA/2013/RR-24	Dr. Vikas L
19.	OPD No 204, 2nd Floor, Homi Bhabha Block, Tata Memorial Centre, Dr. Ernest Borges Road Parel, Mumbai -400012	Institutional Ethics Committee I and II, Tata Memorial Centre, Dr. Ernest Borges Road Parel, Mumbai -400012 EC reg No. ECR/170/Inst/MH/2013/RR-22 ECR/414/Inst/MH/2013/RR-24	Dr. Kumar Prabhash
20.	Amrita Institute of Medical Sciences, AIMS Ponekkara P0, Kochi-682041, Kerala,India	Institutional EthicsC ommittee, Amrita Institute of Medical Sciences, AIMS Ponekkara P0, Kochi-682041, Kerala, India EC reg No. ECR/129/Inst/KL/2013/RR-24	Dr. Pavithran Keechilat
21.	Max Super Speciality Hospital, Nagpur (A unit of Alexis Multispeciality Hospital Pvt Ltd) Clinical Research Department, Basement Floor Survey no.232, House no. 1313, Mankapur Square Koradi Road, Nagpur – 440030 Maharashtra, India	Institutional Ethics Committee Alexis Multi-Speciality Hospital Pvt. Ltd., Mankapur Square Koradi Road Nagpur Maharashtra -440030 India EC reg No. ECR/1430/Inst/MH/2020	Dr. Amol Shankar Dongre
22.	Manipal Hospital, Room No 16. /1stfloor, Department of Medical Oncology, 98, Old Airport Road, Bangalore, 560017, India	Ethics Committee of Manipal Hospitals, Ethics Committee of Manipal Hospitals No 98, Old Airport Road No 98, Old Airport Road Bangalore Bengaluru (Bangalore) Urban Karnataka-560017 India EC reg No. ECR/34/Inst/KA/2013/RR-24	Dr Rauthan Amit Deenabandhu
23.	Malabar Cancer Centre, (PGIOSR), Moozhikkara P O Thalassery, Kannur Kerala, India 670103	Institutional Ethics Committee- Malabar Cancer Centre, Malabar Cancer CentreMoozhikkara P.O Kodiyei Thalassery Kannur Kerala - 670103 India EC reg No. ECR/780/Inst/KL/2015/RR-21	Dr Praveen Kumar Shenoy V P
24.	National Cancer Institute, All India Institute of Medical Science, Room no 110, First Floor, Department of medical oncology, Badsa, Badli, Jhajjar, Haryana, 124105, India	Institute Ethics Committee, All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi Delhi -110029 India EC reg No. ECR/538/Inst/DL/2014/RR-25	Dr Aparna Sharma
25.	BRA IRCH, Department of Medical Oncology, All India institute of medical science, Ansari Nagar, New Delhi, South Delhi, Delhi, 110029 India.	Institute Ethics Committee, All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi Delhi -110029 India	Dr. Deepam Pushpam

		EC reg No. ECR/538/Inst/DL/2014/RR-25	
26.	Rajiv Gandhi Government General Hospital, Madras Medical College, Department of Oncology, 4th Floor, Room Number: 542, GH Post Office, Poonamallee High Road, 3, Southern Trunk Road, Park Town, Near Chennai Central, Chennai, Tamil Nadu-600003.	Madras Medical College, EVR Periyar Salai, Park Town, Chennai, Tamil Nadu-600003, India. EC reg No. ECR/270/Inst/TN/2013/RR-20	Dr Kannan Jayaraman
27.	Old SIC building hematology and medical oncology block, VMMC & Safdarjung Hospital, New Delhi 110029 India.	Institutional Ethics Committee VMMC and SJH VMMC And SAFDARJUNG HOSPITAL, Ring Road Ansari Nagar New Delhi South Delhi Delhi -110029 India EC reg No. ECR/593/Inst/DL/2014/RR-20	Dr Kaushal Kalra
28.	CRS Department, 1st floor National Cancer Institute Khasara No 25, Outer Ring Road, Mouza, Jamtha, Nagpur-441108, Maharashtra India	National cancer Institute Ethics Committee, National Cancer Institute, Khasara No.25 Outer Ring Road Jamtha Nagpur Maharashtra - 441108 India EC reg No. ECR/1130/Inst/MH/2018/RR-21	Dr Murtaza Bohra
29.	Department of Medical Oncology, Block-1, 1st floor, Basavatarakam Indo American Cancer Hospital RI Road No 10, Banjara Hills, Hyderabad, Telangana-500034, India	INSTITUTIONAL ETHICS COMMITTEE, Department of Medical Oncology, Block-1, 1st floor, Basavatarakam Indo American Cancer Hospital RI Road No 10, Banjara Hills, Hyderabad, Telangana-500034, India EC reg No ECR/7/Inst/AP/2013/RR-20	Dr MVT Krishna Mohan
30.	Medical College & Hospital, Kolkata, 88, College Street, Kolkata, West Bengal, 700073	Institutional Ethics Committee for Human Research Medical College, Kolkata Medical College, Kolkata 88, College Street Kolkata West Bengal - 700073 India EC reg No ECR/287/Inst/WB/2013/RR-24	Dr Swarnabindu Banerjee
31.	Jharkhand Cancer Centre Hazaribagh Rd, beside Hanuman Dharmkanta, opposite Furniture planet, Kokar, Ranchi, Jharkhand 834001	Ranchi Urology Centre Institutional Ethics Committee, RANCHI UROLOGY CENTER, Buxi Compound, Behind Shyam Petrol Pump, Bariatu RANCHI Ranchi Jharkhand -834009 India	Dr. Saurabh Kumar

		EC reg No ECR/1626/Inst/JH/2021	
32.	Sanjeevani CBCC USA Cancer Hospital, In front of Jain Mandir, Dawada Colony, Pachpedi Naka, Raipur, Chhattisgarh 492001, India	Sanjeevani Cancer Hospital Ethics Committee, Sanjeevani CBCC USA Cancer Hospital, In front of Jain Mandir, Dawada Colony, Pachpedi Naka, Raipur, Chhattisgarh 492001, India EC reg No ECR/818/Inst/CG/2016/RR-24	Dr. Aniket Thoke
33.	MS & SUM Hospital, K-8, Kalinga Nagar, Khandagiri, Bhubaneswar, Odisha, Pin-751003.	IEC IMS and SUM Hospital IMS and SUM Hospital, K8 Kalinga nagar shampur Bhubaneswar Khordha Orissa -751003 India ECR/627/Inst/OR/2014/RR-20	Dr Soumya Surath Panda
34.	MMFHA, Joshi Hospital 778, Shivaji Nagar, Opposite Kamala Nehru Park, Pune, 411004 Maharashtra, India	IEC MAHARASHTRA MEDICAL RESEARCH, MMF Hospitals Association, Pune. Joshi Hospital 778 Shivajinagar Joshi Hospital 778 Shivajinagar Pune EC reg No ECR/311/Inst/MH/2013/RR-24	Dr. Ranade Anant Bhushan Anil