



File No. BIO/CT/24/000104

Dated: 15-01-2025

To,

M/s Lupin Limited (BIOTECHNOLOGY DIVISION),
Gate No 1156, 1157, 1158, 1159, 1160, Village Ghotawade,
Maharashtra (India) - 412115

Subject: Application for grant of permission to conduct Phase III clinical trial entitled – “A randomized, double-blind, multi-center, active-control, parallel group study to compare efficacy, safety, immunogenicity and pharmacokinetics of Lupin’s Nivolumab (LUBT022) with Innovator’s Nivolumab in patients with locally advanced or metastatic non-small cell lung cancer” as per Protocol No. LRP/ LUBT022/2024/002 dated 09-Dec-2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/45046 dated 24.08.2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/45046 dated 24.08.2024, 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) CSR shall be submitted to this office after completion of trial.

- (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 Licensing 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 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;
- (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 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;
- (IX) 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.
- (X) 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.
- (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 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.
- (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 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.
- (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 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.
- (XIV) 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.
- (XV) 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.
- (XVI) 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.
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVIII) 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.

RAJEEV SINGH
RAGHUVANSHI

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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 Lupin Limited (BIOTECHNOLOGY DIVISION), Gate No 1156, 1157, 1158, 1159, 1160, Village Ghotawade, Maharashtra (India) – 412115 to conduct Phase III clinical trial titled- “A randomized, double-blind, multi-center, active-control, parallel group study to compare efficacy, safety, immunogenicity and pharmacokinetics of Lupin’s Nivolumab (LUBT022) with Innovator’s Nivolumab in patients with locally advanced or metastatic non-small cell lung cancer” as per Protocol No. LRP/ LUBT022/2024/002 dated 09-Dec-2024 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. 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: 15.01.2025

**RAJEEV SINGH
RAGHUVANSHI**

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(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:	Nivolumab 10mg/mL (r-DNA origin) solution for intravenous infusion		
Therapeutic class	Anti cancer		
Dosage form:	Nivolumab is available in 10 mL (100 mg/10 mL) and 4 mL (40 mg/4 mL) vial for intravenous infusion.		
Composition:	Each mg/mL contains-		
	Name of Ingredients	Function	Quantity (mg/mL)
	Nivolumab, In house	Active substance	10
	L-Histidine, B.P.,J.P.,Ph.Eur	Buffer component	3.10
	Mannitol, B.P.,I.P.,U.S.P.,J.P.,Ph.Eur	Tonicity agent	30.0
	Sodium Chloride, Ph. Eur. BP, USP, JP, IP	Ionic agent	2.92
	Pentetic acid, U.S.P.	Chelating agent	0.008
	Polysorbate-80, B.P.,I.P.,U.S.P.,J.P.,Ph.Eur	Surfactant	0.2
	Hydrochloric acid, IP, Ph. Eur. BP, USP and JP	pH adjuster	q.s.
	Sodium hydroxide	pH adjuster	q.s.
Water for injection	Vehicle	q.s.	
Indications:	Locally advanced or metastatic non-small cell lung cancer		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	PP Maniya Hospital Private LTD. Mamta Park Society-1 opp. Dharuka College, Kapodra, Surat, Gujarat-395006	PP Maniya Hospital Ethics Committee PP Maniya Hospital Pvt Ltd EC reg no. ECR/1961/Inst/GJ/2024	Dr. Anshul Agarwal
2.	Sparsh Hospital & Critical care Pvt. Ltd., A/407, Saheed Nagar, Bhubaneshwar-751007	Institutional Ethics Committee Sparsh Hospital and Critical Care Private limited EC Reg No. ECR/68/Inst/OR/2013/RR-22	Dr. Ghanshayam Biswas
3.	Kiran Hospital Multi Super Speciality Hospital and Research Center, Near Sumul Dairy, Surat, Gujarat-395004	Kiran Hospital Ethics Committee EC Reg No ECR/1029/Inst/GJ/2018/RR-21	Dr. Priyanka Das

4.	HCG Cancer Centre, plot no. 10, survey no. 13P APIIC Health City, Arilova. Chinnagadili, Vishakhapatnam 530040	Institutional Ethics Committee HCG Cancer Centre EC Reg No ECR/864/Inst/AP/2016/RR-20	Dr. Sanketh Kotne
5.	Spandana Oncology Centre, #919, New No. 68. 28th Main Road, 9th block, Jayanagar, Bangalore-560068	Institutional Ethics Committee Spandana Oncology Centre EC Reg No ECR/1950/Inst/KA/2024	Dr. Satheesh C T
6.	Shalby Hospital, Opp. Karnvati Club, S.G. Highway, Ahmedabad-380015, Gujarat, India	Institutional Ethics Committee Ethics Committee -Shalby Limited EC Reg No ECR/711/Inst/GJ/2015/RR-21	Dr. Viraj Lavangia

