



File No. BIO/CT/23/000093

Dated 20-11-2024

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

Subject: Application for grant of permission to conduct Phase IV clinical trial titled – “A Prospective, Multi-center, Single-arm, Phase IV Study to Assess the Safety, Efficacy and Immunogenicity of Ranibizumab Solution for Injection 10 mg/mL (r-DNA Origin).” vide Protocol No. ICR/23/004, Version No. 3.0 dated 09.07.2024– regarding Ref.: Your Application No BIO/CT04/FF/2023/38367 dated 12-07-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2023/38367 dated 12-07-2024, 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) 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;
- (II) 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;
- (III) 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;
- (IV) 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;
- (V) 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;
- (VI) 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;
- (VII) 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;
- (VIII) 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;

- (IX) 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;
- (X) 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;
- (XI) 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;
- (XII) 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;
- (XIII) 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 authorised 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;
- (XIV) 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;
- (XV) 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;
- (XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVII) 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 Licensing 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.
- (XVIII) 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 Licensing Authority.
- (XIX) The firm should submit Clinical study report (CSR) to this office after completion of trial.

Yours faithfully,

RAJEEV SINGH
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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 Licencing Authority hereby permits **M/s Sun Pharmaceutical Industries Limited, Tandalja Vadodara Vadodara (India) – 390012** to conduct clinical trial of the new drug or investigational new drug study titled – “A Prospective, Multi-center, Single-arm, Phase IV Study to Assess the Safety, Efficacy and Immunogenicity of Ranibizumab Solution for Injection 10 mg/mL (r-DNA Origin).” vide Protocol No. ICR/23/004, Version No. 3.0 dated 09.07.2024 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.

Place: New Delhi

Date: 20.11.2024

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Annexure:**Details of new drug or investigational new drug:**

Name of the new drug to be manufactured	Ranibizumab Solution for Injection 10 mg/mL (r-DNA Origin)		
Dosage form:	Single-use glass vial for intravitreal injections		
Composition:	Each ml contains:		
	Name of Ingredient	Quantity per ml (mg/ml)	Function
	Ranibizumab IH	10	Active Pharmaceutical Ingredient
	L-Histidine hydrochloride monohydrate Ph. Eur.	1.662	Buffer component
	L-Histidine Ph. Eur	0.321	Buffer component
	α - α Trehalose dihydrate USP	100	Stabilizer/Tonicity Modifier
	Polysorbate-20 IP	0.1	Surfactant / Stabilizer
	Water for Injection IP	q.s. to 1.0 mL	Solvent
Indication:	Indicated for treatment of the patients with: <ul style="list-style-type: none"> • Neovascular age-related macular degeneration (AMD) • Diabetic macular oedema (DME) • Macular oedema following retinal vein occlusion (RVO) • Visual impairment due to choroidal neovascularization (CNV) secondary to pathological myopia (PM) 		
Shelf life with storage condition:	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Protect from light. Prior to use, the unopened vial may be kept at room temperature (25°C) for up to 24 hours.		

Details of clinical trial site:

S. No	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Department of Ophthalmology, Postgraduate Institute of Medical Education and Research, Room no 223, Sector-12, Chandigarh 160012	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research, Chandigarh. ECR/25/Inst/CH/2013/RR-20	Dr. Basavaraj Tigari
2	Department of Ophthalmology, Regional Institute of	Institutional Ethics Committee, Regional	Dr. Lakshmi Kanta

	Ophthalmology, H9F5+FPQ Administrative Block, Medical College & Hospital, Kolkata, 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073	Institute of Ophthalmology, Kolkata ECR/59/Inst/WB/2013/RR- 19	Mondal
3	Government Eye Hospital, M & J Institute of Ophthalmology, Director Office Manjushri Mill, Compound, Asarwa, Ahmedabad- 380016, Gujarati India.	Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Ahmedabad. ECR/72/Inst/GJ/2013/RR- 19	Dr. Gonsai Jigneshgiri Yashvantgiri
4	Dr R. S. P. R Govt Regional Eye Hospital, Opposite Bullaya College, Resapuvanipalem, Visakhapatnam-530013, Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Visakhapatnam. ECR/197/Inst/KGH/2013/R R-20	Dr. Penumala Viswamithra
5	Disha Eye Hospitals Pvt. Ltd, 14, Grand Trunk Rd, Sheoraphuli, West Bengal - 712223	Disha Eye Hospitals Pvt. Ltd, Ethics Committee, Kolkata. ECR/846/Inst/WB/2016/RR -19	Dr. Debdulal Chakraborty
6	Netralaya Super Speciality Hospital, 1st Floor, Kay DEE House, Above Union Bank, Parimal Garden Cross Road, Chimanlal Girdharlal Rd, Ambawadi, Ahmedabad, Gujarat 380006	Swarnim Ethics Committee, Ahmedabad ECR/1922/Inst/GJ/2024	Dr. Rana Parth Jagdishkumar
7	Sunayan Advanced Eye Institute, Salgechia, Tamluk, Purba Medinipur, West Bengal, Pin no- 721636	Sunayan Advanced Eye Institute, Medinipur, West Bengal. ECR/1537/Inst/WB/ 2021	Dr. Jayanta Kuila