



File No. BIO/CT/24/000120

Dated 04-04-2025

To,

M/s Reliance Life Sciences Pvt
Ltd , Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC,
Thane -Belapur Road,
Rabale Navi Mumbai (India) - 400701.

Subject: Application for grant of permission to conduct Phase I/III clinical trial titled – “A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of R-TPR-051 (RLS-Aflibercept) and Eylea® administered by intravitreal injection in Patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD)” vide Protocol No.RLS/OPT/2024/04 Version2.0, Dated 23 Sep 2024– regarding

Ref.: Your Application No BIO/CT04/FF/2024/45392 dated 30-09-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2024/45392 dated 30-09-2024, 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 firm has to submit validated Bioanalytical method (STP) for pK study to this office in due course of time

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,
Digitally signed by RAJEEV SINGH RAGHUVANSHI
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RAJEEV SINGH RAGHUVANSHI
(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 Reliance Life Sciences Pvt Ltd , Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC, Thane -Belapur Road,Rabale Navi Mumbai (India) – 400701** to conduct clinical trial of the new drug or investigational new drug study titled – “A Prospective, Multicenter, Randomized, Double-Blind, Parallel-Group, Two-Arm Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of R-TPR-051 (RLS-Aflibercept) and Eylea® administered by intravitreal injection in Patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD)” vide Protocol No.RLS/OPT/2024/04 Version2.0, Dated 23 Sep 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: 07.04.2025

**RAJEEV SINGH
RAGHUVANSHI**

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

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

Name of the new drug to be manufactured	Aflibercept Injection 40 mg/ml, (2mg/0.05ml PFS/Vial)		
Therapeutic Class	VEGF Inhibitor		
Dosage form:	Solution for injection		
Composition:	Each ml contains:		
	Name of Ingredient	Quantity per PFS/Vial	Function
	Aflibercept, In house	40 mg/ml	Active Ingredient
	Sodium chloride, Ph.Eur/IP	40mM	Buffer
	Polysorbate-20, Ph. Eur./IP	0.03%	Surfactant
	Sucrose, Ph.Eur/IP	5%	Stabilizer
	Sodium phosphate monobasic monohydrate, BP/IP	10mM	Buffer
	Sodium phosphate dibasic heptahydrate, USP/Ph.Eur		
	Water for Injection, Ph.Eur/USP/IP	q.s.	Diluent
Indication:	For the treatment of neovascular (wet) age-related macular degeneration (wet AMD)		

Details of clinical trial site:

S.No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Amrita Institute of Medical Sciences, AIMS, Ponekkara P.O, Kochi Kerala -682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS, Ponekkara P.O, Kochi Kerala -682041 EC Reg. No.: ECR/129/INST/KL/2013/RR-19	Dr Gopal S Pillai

2	Netralaya Super Speciality Hospital,, 1st Floor, KayDee House, Above Union Bank of India, Oppo Gujarat Gas, Piramal Garden Cross Road, CG Road Ahmedabad Gujarat-380006	Swarnim Ethics Committee,Netralaya Super Speciality Eye Hospital,1st Floor KayDee House, Opp. Gujarat Gas, Parimal Garden Cross Road, Ellisbridge, Ahmedabad –380006 Gujarat India EC Reg. No.: ECR/1922/Inst/GJ/2024	Dr Parth Rana
3	Regional Institute of Ophthalmology, 88, College Street Kolkata West Bengal - 700073	INSTITUTIONAL ETHICS COMMITTEE, Regional Institute of Ophthalmology, , 88, College Street Kolkata West Bengal - 700073 EC Reg. No.: ECR/59/Inst/WB/2013/RR-19	Dr LK Mondal
4	Dr. D.Y. Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri Pune Maharashtra - 411018	Ethics Committee, Dr. D.Y.Patil Vidyapeeth Pune, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India EC Reg. No.: ECR/361/Inst/MH/2013/RR-24	Dr Nilesh Giri
5	Department of Ophthalmology Charak Bhawan, OPD Block SMS Hospital Jaipur Rajasthan - 302004	Ethics Committee, S.M.S. Medical College and Attached Hospitals,JLN Marg,Jaipur-302004,Rajasthan EC Reg. No.: ECR/26/Inst/RJ/2013/RR-19	Dr Khushbhu Jindal
6	All India Institute of Medical Sciences, Plot no-2, Sector 20, MIHAN Nagpur Maharashtra - 441108	Institutional Ethics Committee for Clinical Trial, All India Institution of Medical Sciences, Plot no-2, Sector 20, MIHAN Nagpur Maharashtra - 441108 EC Reg. No.: ECR/1392/INST/MH/2020	Dr Vandana Iyer
7	All India Institute of Medical Sciences, G.E. Road, Tatibandh Raipur -492099, Chhattisgarh, India	Institution Ethics CommitteeAIIMS, Raipur,Room No. 2103, Second floor, Medical College Complex, Gate No. 05, Tatibandh, Raipur-492099, Chhattisgarh, India EC Reg. No.: ECR/714/Inst/CT/2015/RR-21	Dr Vijaya Sahu
8	JLN Medical College and attached Hospital, Opp.Patel stadium Ajmer Rajasthan - 305001	Institutional Ethics Committe, Jawahar Lal Nehru Medical College, Kala Bagh,Ajmer-305001,Rajasthan EC Reg. No.: ECR/1156/Inst/RJ/2018/RR-22	Dr Rakesh Porwal
9	Career Institute of Medical Sciences and Hospital, Near IIM, Ghaila Lucknow Uttar Pradesh - 226020	The Institutional Human EC, UdyaanHealth Care, 730, Udyaan-1, Eldeco, Near Bangla Bazar, Lucknow-226020, Uttar Pradesh, India EC Reg. No.:	Dr Vijay Kumar Singh

		ECR/1300/Inst/UP/2019	
10	Department of Ophthalmology, Belgavi Institute of Medical Sciences, Belgavi Dr B R Ambedkar Road Belagavi Karnataka - 590001	Institutional Ethics Committee, BIMS, 3rd Floor, BIMS Building, Dr B R Ambedkar Road, Belagavi-590001, Karnataka India EC Reg. No.: ECR/801/Inst/KA/2016/RR-20	Dr Sandip Patil
11	Department of Ophthalmology, K R Hospital, Attached to Mysore Medical College and Research Institute, Irwin Road Mysuru, Karnataka - 570001	Institutional Ethics Committee, Mysore Medical College and Research Institute and Associated Hospital, Mysuru-570001 EC Reg. No.: ECR/134/Inst/KA/2013/RR-19	Dr Satish K
12	M and J Western Regional Institute of Ophthalmology, A Unit of B.J Medical College, Badiya Limbdi Char Rasta, New Civil Hospital Campus, Asarwa Ahmedabad Gujarat - 380016	Institutional Ethics Committee, B. J. Medical College & Civil Hospital Office of the superintendent, New Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India EC Reg. No. ECR/72/Inst/GJ/2013/RR-24	Dr Neha Desai
13	Sankara Eye Hospital, Varthur Main Road, Kundanahalli Gate Bangalore Karnataka - 560037	Institutional Ethics Committee, Sankara Eye Hospital, Varthur Main Road, Kundanahalli Gate, Bangalore-560037, Karnataka, India EC Reg. No.: ECR/705/Inst/KA/2015/RR-21	Dr Minija CK
14	Sankara Eye Hospital, Sathy Road, Sivanandapuram Coimbatore Tamil Nadu - 641035	Institutional Ethics Committee, Sankara Eye Hospital, Sathy Road, Sivanandapuram, Coimbatore-641035, Tamilnadu, India EC Reg. No.: ECR/512/Inst/TN/2014/RR-20	Dr Prabhu Shanker
15	Lotus Eye Hospital and Institute Limited, Avinashi Road, Civil Aerodrome Post Coimbatore Tamil Nadu - 647014	Institutional Human Ethics Committee Academic block, 1st floor, PSG institute of Medical Science and Research Centre, Avinashi Road, Peelamedu, Coimbatore -641004, Tamilnadu, India EC Reg. No.: ECR/252/Inst/TN/2013/RR-19	Dr Ashish Sharma
16	Drishtipunj Eye Hospital Pvt Ltd, Vishwasharaiya Nagar, Bailey Road, Patna Bihar - 801503	Institutional Ethics Committee, BSL Eye Care, Road no 2B, Rajendra Nagar, Patna-800016, Bihar, India EC Reg. No.: ECR/1328/Inst/BR/2019	Dr Bandana Kumari

17	Dr. Jawahar Lal Rohatgi Smarak Netra Chikitsalaya,, Sarvodaya Nagar, Kanpur Uttar Pradesh - 208005	Ethics Committee Raja Nursing Home, Raja Nursing Home, Arazi no 152 Brahm Nagar Bithoor Kanpur-209217, Uttar Pradesh, India EC Reg. No.: ECR/1993/Inst/UP/2024	Dr Sukant Pandey
18	Kashyap Memorial Eye Hospital Pvt. Ltd., Purulia Rd, Near Dangratoli Chowk, Dangratoli, Nayatoli Ranchi Jharkhand - 834001	Institutional Eth CS Committee, Kashyap Memorial Eye Hospital, Kashyap Memorial EyeHospital Complex, Near Dangratoli Chowk,Dangratoli, Nayatoli ,Ranchi, 834001, Jharkhand, India EC Reg. No.: ECR/1790/Inst/JH/2023	Dr Bibhuti P Kashyap
19	Modern Eye Hospital, 11- 13-G, Suyojit Modern Point, Opposite Police Parade Ground, Sharanpur Road Nashik Maharashtra - 422002	Magna-care Ethics Committee, Chopda Medicare & Research Centre Pvt. Ltd; Magnum Heart Institute, Nashik-422005 EC Reg. No.: ECR/79/Inst/MH/2013/RR-24	Dr Rohit Sanjay Laul
20	Sadguru Netra Chikitsalaya, Shri Sadguru Seva Sangh Trust, Jankikund, Chitrakoot Chitrakoot Madhya Pradesh - 210204	Shri Sadguru Seva Sangh Trust, Shri Sadguru Seva Sangh Trust, Jankikund, Chitrakoot-210204, Satna, MP, India EC Reg. No.: ECR/1403/Inst/MP/2020	Dr Alok Sen
21	Insight Institute of Ophthalmology and Laser Center, Godawoon chowk, Spine road, Bhosari, Pune-411039, Maharashtra, India	Institutional Ethics Committee, Insight Institute of Ophthalmology, Godawoon chowk, Spine road, Bhosari, Pune-411039 EC Reg. No.: ECR/1027/INST/MH/2018/RR-21	Dr. Anjali Sapar
22	Minto Ophthalmic Hospital, BMC & RI, Chamrajpet, Tippu Sultan Palace Road, opposite V. V. Puram Police Station, New Tharagupet, Bangalore-560002	Ethics Committee of BMCRI, Bangalore Medical College and Research Institute, Fort, K R Road, Bangalore-560002, Karnataka, India EC Reg. No.: ECR/302/Inst/KA/2013/RR-20	Dr. Shashidhar S
23	GMERS Medical College and Civil Hospital Sola, Department of Ophthalmology, Nr. Gujarat High Court, S. G. Highway, Sola Ahmedabad, 380060, Gujarat, India	Institutional Ethics Committee, GMERS Medical College Sola, 4thFloor, Department of Pharmacology, S.G. Highway, Nr. Gujarat High Court, Ahmedabad- 380061, Gujarat, India. EC Reg. No.: ECR/404/Inst/GJ/2013/RR-20	Dr. Deepika Singhal