



File No. BIO/CT/24/000078

Dated: 15-01-2025

To,

M/s Reliance Life Sciences Pvt Ltd,
Dhirubhai Ambani Life Sciences Centre, R-282, TTC area of MIDC, Thane Belapur road,
Rabale, Navi Mumbai, Maharashtra (India) - 400701

Subject: Application for grant of permission to conduct Phase II/III clinical trial entitled – “A prospective, multicentre, randomized, open label, two-arm, parallel group, active control, comparative phase II / phase III clinical study to evaluate efficacy, safety and immunogenicity of R-TPR-023(RLS-Bevacizumab)/ Accentrix® (Ranibizumab) in patients with neovascular (wet) age-related macular degeneration” as per Protocol No. RLS/OPT/2024/03 Version 2.0, Dated 08 Oct 2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/44147 dated 10.07.2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/44147 dated 10.07.2024, 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. Further based on your request vide application BIO/CT04/FF/2024/44147 dated 10.07.2024 to allow the use of Bevacizumab Injection 5 mg/0.2mL manufactured under CT11/BIO/23/000074 dated 06-Jun-2023 for clinical trial purpose, this office has no objection to your request to use 3000 vials of Bevacizumab Injection 5 mg/0.2mL manufactured in GMP facility under CT-11 permission (CT11/BIO/23/000074) in the subject clinical trial

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;

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 Reliance Life Sciences Pvt Ltd, Dhirubhai Ambani Life Sciences Centre, R-282, TTC area of MIDC, Thane Belapur road, Rabale, Navi Mumbai, Maharashtra (India) – 400701 to conduct Phase II/III clinical trial entitled– “A prospective, multicentre, randomized, open label, two-arm, parallel group, active control, comparative phase II / phase III clinical study to evaluate efficacy, safety and immunogenicity of R-TPR-023(RLS-Bevacizumab)/ Accentrix® (Ranibizumab) in patients with neovascular (wet) age-related macular degeneration” as per Protocol No. RLS/OPT/2024/03 Version 2.0, Dated 08 Oct 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

Digitally signed by 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:	Bevacizumab 25mg/mL (r-DNA origin) solution for intravitreal injection	
Therapeutic class	Monoclonal Antibodies	
Dosage form:	Single dose vial of 5mg/0.2ml for ophthalmic use	
Composition:	Each mL contains-	
	Name of Ingredients	Quantity (mg/mL)
	Bevacizumab (r-DNA Origin) IH	25 mg
	Sodium Phosphate (monobasic monohydrate) IP/B.P/USP	5.8 mg
	Sodium Phosphate (dibasic anhydrous) Ph. Eur	1.2 mg
	Polysorbate 20 IP/Ph.Eur/USP	0.4 mg
	Trehalose dehydrate Ph. Eur	60 mg
	Water For Injection IP/BP/USP	QS to 1.0mL
Indications:	Neovascular wet age related macular degeneration	

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, Charak Bhawan, OPD Block, SMS Hospital, Jaipur 302004, Rajasthan, India	Ethics Committee- Department of Ophthalmology, Charak Bhawan, OPD Block, SMS Hospital, Jaipur 302004, Rajasthan, India EC reg no. ECR/26/Inst/RJ/2013/RR-19	Dr. Sandeep Parwal
2.	Insights Institute of Ophthalmology and Laser centre, Godawoon chowk, Spine road, Bhosari, Pune-411039, Maharashtra, India	Ethics Committee- Insights Institute of Ophthalmology and Laser centre, Godawoon chowk, Spine road, Bhosari, Pune-411039, Maharashtra, India EC reg no. ECR/1027/INST/MH/2018/RR-21	Dr. Anjali Sappar
3.	D Y Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri, Pune -411018, Maharashtra	Ethics Committee- D Y Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri, Pune -411018, Maharashtra EC reg no. ECR/361/Inst/MH/2013/RR-19	Dr. Nilesh Giri

4.	Netralaya Super Speciality Hospital, 1st Floor, KayDee House, Above Union Bank of India, Oppo Gujarat Gas, Piramal Garden Cross Road, CG Road, Ahmedabad - 380006, Gujarat, India	Ethics Committee-Netralaya Super Speciality Hospital, 1st Floor, KayDee House, Above Union Bank of India, Oppo Gujarat Gas, Piramal Garden Cross Road, CG Road, Ahmedabad -380006, Gujarat, India EC reg no. ECR/1922/Inst/GJ/2024	Dr. Parth Rana
5.	Department of Ophthalmology, K. R. Hospital, Attached to M.M.C & RI, Irwin road, Mysore-570001, Karnataka, India	Ethics Committee- Department of Ophthalmology, K. R. Hospital, Attached to M.M.C & RI, Irwin road, Mysore-570001, Karnataka, India EC reg no. ECR/134/Inst/KA/2013/RR-19	Dr. Sandhya Dharwadkar
6.	Regional Institute of Ophthalmology 88 College Street, Kolkata -700073, West Bengal, India	Ethics Committee- Regional Institute of Ophthalmology 88 College Street, Kolkata -700073, West Bengal, India EC reg no. ECR/59/Inst/WB/2013/RR-19	Dr. Fariduddin Khandkar
7.	NRS Medical College and Hospital, 138 AJC Bose Road, Kolkata 700014, West Bengal, India	Ethics Committee- Regional Institute of Ophthalmology 88 College Street, Kolkata -700073, West Bengal, India EC reg no. ECR/609/Inst/WB/2014/RR-20	Dr. Krishnapada Baidya
8.	M & J Western Regional Institute of Ophthalmology, Badiya Limbdi Char Rasta, New Civil Hospital Campus, Asarwa, Ahmedabad -380016, Gujarat, India	Ethics Committee- M & J Western Regional Institute of Ophthalmology, Badiya Limbdi Char Rasta, New Civil Hospital Campus, Asarwa, Ahmedabad - 380016, Gujarat, India EC reg no. ECR/72/Inst/GJ/2013/RR-19	Dr. Neha Desai
9.	Dr. D Y Patil Medical College Hospital and Research Centre, Sector 5, Nerul, Navi Mumbai-400706	Ethics Committee- Dr. D Y Patil Medical College Hospital and Research Centre, Sector 5, Nerul, Navi Mumbai-400706 EC reg no. ECR/195/Inst/MH/2013/RR-19	Dr. Archana Tadwalkar

10.	SBKS MI & RC Dhiraj Hospital, Department of Ophthalmology, Sumandeep Vidhyapeeth Deemed to be University, at & Po Piparia, Ta. Waghodia, Vadodara -391760, Gujarat, India	Ethics Committee- Dr. D Y Patil Medical College Hospital and Research Centre, Sector 5, Nerul, Navi Mumbai-400706 EC reg no. ECR/152/Inst/GJ/2013/RR-19	Dr. Punit kumar Singh
11.	Birla eye hospital 9-G-8, 3rd, Mahaveer Nagar Housing Board Colony, Mahaveer Nagar, Kota –324005, Rajasthan, India	Ethics Committee- Birla eye hospital 9-G-8, 3rd, Mahaveer Nagar Housing Board Colony, Mahaveer Nagar, Kota –324005, Rajasthan, India EC reg no. ECR/1094/Inst/RJ/2018/RR-21	Dr. Shailendra Birla

