



Government of India  
Central Drugs Standard Control Organisation (Headquarter)  
(Directorate General of Health Services)  
FDA Bhavan, ITO, Kotla Road  
New Delhi - 110002 (Delhi)  
Phone No.: 91-11-23216367  
Fax No.: 91-11-23236973  
E-Mail: dci@nic.in

File No. BIO/CT/23/000092

Dated 20-09-2024

To,

M/s Roche Products (India) Private Limited,  
146 B, 166 A, Unit No 7,8,9, 8<sup>th</sup> floor, R city office, R City Mall  
Lal Bahadur Shastri Marg, Ghatkopar (West)  
Mumbai (India) – 400086

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled – " A Phase IV, Multicenter, Open-Label, Single-Arm study in Patients with Neovascular Age-Related Macular Degeneration or Diabetic Macular Edema to evaluate the Safety and Effectiveness of the Faricimab Intravitreal Injection in India (Vitreal Study)" as per Protocol No.: ML45007, Version 2.0, dated: 29.04.2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/38418 dated 12.07.2023

Sir,

With reference to your application No.: BIO/CT04/FF/2023/38418 dated 12-JUL-2023, 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) You are required to submit the Clinical study report after completion of study to this office.
- (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.

RAJEEV SINGH  
RAGHUVANSHI  
Yours faithfully,

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
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(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 Roche Products (India) Private Limited, 146 B, 166 A, Unit No 7,8,9, 8<sup>th</sup> floor, R city office, R City Mall Lal Bahadur Shastri Marg, Ghatkopar (West) Mumbai (India) – 400086 Telephone No.: 22-33941443, 22-33941415, 22-33941413 FAX: 22-33941054 E-Mail : VIPUL.GUPTA@ROCHE.COM to conduct Phase IV clinical trial entitled **"A Phase IV, Multicenter, Open-Label, Single-Arm study in Patients with Neovascular Age-Related Macular Degeneration or Diabetic Macular Edema to evaluate the Safety and Effectiveness of the Faricimab Intravitreal Injection in India (Vitreal Study)"** as per Protocol No.: ML45007, Version 2.0, dated: 29.04.2024 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-Sep-2024

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:	Faricimab 6 mg/0.05 mL (120mg/mL) solution for intravitreal injection in a single dose vial with filter transfer needle (r-DNA origin)		
Therapeutic class	Anti-vascular endothelial growth factor (VEGF)-A and anti-angiopoietin-2(Ang-2) antibody.		
Dosage form:	Intravitreal solution for injection		
Composition:	Each single-use 2mL vial contains:		
	<b>Name of Ingredients</b>	<b>Specifications</b>	<b>Quantity (per vial)</b>
	Faricimab	IH	6 mg
	L-Histidine	USP-NF/Ph. Eur/JP	155 mcg
	Acetic Acid 30%	Ph. Helv*	qs to pH 5.5
	L-Methionine.	USP-NF/Ph. Eur/JP	52.2 mcg
	Sodium Chloride	USP-NF/Ph. Eur/JP	73.1 mcg
	D-Sucrose	USP-NF/Ph. Eur/JP	2.74 mg
	Polysorbate 20	USP-NF/Ph. Eur/JPE	20.0 mcg
	Water for Injection	USP-NF/Ph. Eur/JP	QS to 0.05 mL
	<i>*Manufactured by supplier from glacial acetic acid USP-NF/Ph. Eur/JP</i>		
Indications:	Indicated for the treatment of: <ul style="list-style-type: none"> <li>• Neovascular(wet) age-related macular degeneration (nAMD)</li> <li>• Diabetic macular edema (DME)</li> </ul>		

**Details of clinical trial site:**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Banker's Retina Clinic & Laser Centre 5 Subhash Society, Behind Ishvar Bhuvan, Navrangpura, Ahmedabad, Gujarat, 380009,India	Independent Ethics Committee of Health and Care Foundation Hospital Health and Care Foundation Hospital Part A, Seva Sansthan, Near Rajwadu, Near Malavtalav, B/H Sunflower, Vejalpur, Ahmedabad , Gujarat - 380051 India EC Reg. No.: ECR/1208/Inst/GJ/2019/RR-22	Dr. Alay Banker
2.	Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, Ansari Nagar, New Delhi, 110023 - India	Institute Ethics Committee for biomedical and Health Research All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New-Delhi – 29 City, 110029-India EC Reg. No.: EC/NEW/INST/2022/DL/0144	Dr. Shorya Azad
3.	Centre for Sight Eye Institute , B5/24, Safdarjung Enclave, Opposite Deer Park,	Centre for Sight Institutional Ethics Committee, Centre for Sight Eye Institute ,	Dr. Dinesh Talwar

	Humayunpur, New Delhi - 110029 India	B5/24, Safdarjung Enclave, Opposite Deer Park, Humayunpur, New Delhi - 110029 India  EC Reg. No.: ECR/955/Inst/DL/2017/RR-20	
4.	Regional Institute of Ophthalmology 88 College Street, Kolkata -West Bengal, 700 073- India	Institutional Ethics Committee Regional Institute of Ophthalmology 88 College Street, Kolkata -700 073, West Bengal, India EC Reg No.: ECR/59/Inst/WB/2013/RR-19	Dr. Asim Kumar Ghosh
5.	L V Prasad Eye Institute Kallam Anji Reddy Campus, L.V. Prasad Marg, Banjara Hills, Hyderabad, Telangana, India, 500034 - India	L V Prasad Eye Institute Ethics Committee, LV Prasad Marg, Banjara Hills, Road No: 02 Hyderabad - Telangana, 500034. India EC Reg. No. ECR/468/Inst/AP/2013/RR-19	Dr. Brijesh Takkar
6.	Amrita Institute of Medical Sciences, Kochi, AIMS- Ponekkara P.O, Kochi, 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences, Kochi, AIMS Ponekkara P.O, Kochi, 682041 EC Reg No. ECR/129/Inst/KL/2013/RR-19	Dr. Gopal Pilai