सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
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. CT/25/000004

To,

M/s PFC Pharma Focus India Private Limited,
Plot No. 121, Basement, Pocket - 1, Jasola,
New Delhi – 110025 (India).

Sir,

With reference to your application No. GCT/CT04/FF/2025/47293 dated 18-Jan-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Phase 3, Multicenter, Double-Masked, Randomized, Parallel Group Study to Evaluate the Efficacy and Safety of Intravitreal OTX-TKI (Axitinib Implant) in Subjects with Neovascular Age-Related Macular Degeneration" Protocol No. OTX-TKI-2023-AMD-303, Version 4.0 dated 20-Nov-2024 with a total of up-to 250 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

1) **Human biological samples i.e. Human blood (whole) and Ophthalmic Images related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
2) 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 Licencing Authority under rule 8;
3) 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;
4) 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;
5) the Central Licencing 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;
6) 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;

7) 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;

8) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

9) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

10) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

11) 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 Licencing 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;

12) 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

13) 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

14) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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;

15) 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 Licencing 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;

16) 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;

17) the Central Licencing 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;

18) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

19) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

20) 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 Licencing Authority.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.04.09 15:43:09 +05'30'

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

(See rules 22,25,26,29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

1. The Central Licensing Authority hereby permits **M/s PFC Pharma Focus India Private Limited, Plot No. 121, Basement, Pocket - 1, Jasola New Delhi - 110025 New Delhi (India) - 110025 Telephone No.: 9810609285 FAX: 1203101585 E-Mail : SAUREN@PFCPHARMA.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. OTX-TKI-2023-AMD-303, Version 4.0 dated 20-Nov-2024** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational 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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.04.09 15:43:28 +05'30'

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

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:
Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Axitinib (OTX TKI)
Therapeutic class:	Anti VEGF
Dosage form:	Injection
Composition:	Repurified 4A 20k PEG SAZ=0.1400 milligram (mg) In House Specification Inactive Sodium Phosphate Dibasic Dried USP =0.0200 milligram (mg) U.S.P. Inactive Axitinib (Form IV), Micronized=0.4500 milligram (mg) In House Specification Active Sodium Phosphate Monobasic Anhydrous USP =0.0100 milligram (mg) U.S.P. Inactive Recrystallized 8A 20k PEG Free Amine =0.0700 milligram (mg) In House Specification Inactive
Indications:	Neovascular Age-Related Macular Degeneration (nAMD)

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Dr. Rajendra Prasad Centre For Ophthalmic Sciences, All India Institute of Medical Sciences AIIMS, Campus, Ansari Nagar East Delhi Delhi- 110029	Institute Ethics Committee ECR/538/Inst/DL/2014/RR-20	Dr Pradeep Venkatesh
2.	Government Eye Hospital - Mand J Institute of Ophthalmology, Room No. - 268, Manjushree Mill Compund, Balya Limdi Cross Road, Asarwa Ahmedabad Gujarat -380016	INSTITUTIONAL ETHICS COMMITTEE - B. J. MEDICAL COLLEGE AND CIVIL HOSPITAL ECR/72/Inst/GJ/2013/RR-24	Dr Jignesh Gosai
3.	Dr Shroffs Charity Eye Hospital, 5027, Kedarnath Ln, opposite DAV School, Daryaganj Delhi Delhi - 110002	Dr. Shroff Charity Eye Hospital Ethics Committee ECR/64/Inst/ND/2013/RR-24	Dr Manisha Agarwal
4.	SMS Medical College and attached Hospital, Jawahar LalNehru Marg, Ashok Nagar Jaipur Rajasthan - 302004	SMS Medical College and Attached Hospital Ethics Committee ECR/26/Inst/RJ/2013/RR-24	Dr Sandeep Parwal
5.	Aravind Eye Hospital and Postgraduate Institute of Ophthalmology, No.1 Anna Nagar Madurai Tamil Nadu - 625020	Institutional Ethics Committee ECR/182/Inst/TN/2013/RR-19	Dr Naresh Babu
6.	Sankara Nethralaya, Medical Research Foundation, Padmabhusan Dr. S.S. Badrinath Campus, 41-18, College Road, Nungambakkam Chennai Tamil Nadu - 600006	Institutional Review Board -Ethics Committee ECR/162/Inst/TN/2013/RR-24	Dr Muna Bhende
7.	L V Prasad Eye Institute, Kallam Anji Reddy Campus, LV Prasad Marg, Banjara Hills,Road No 2 Hyderabad Telangana - 500034	L V Prasad Eye Institute Ethics Committee ECR/468/Inst./AP/2013/RR-19	Dr Ritesh Narula
8.	PBMAs H V Desai EyeHospital, 93, Tarawade Vasti, Mohammadwadi, Hadapsar Pune Maharashtra - 411060	Institutional Ethics Committee ECR/234/Inst/MH/2013/RR-22	Dr Sucheta Kulkarni
9.	ICARE Eye Hospital and Post Graduate Institute, E-3A, Sector26, Noida Noida Uttar Pradesh- 201301	ICARE EYE HOSPITAL AND PGI ETHICS ECR/393/Inst/UP/2013/RR-24	Dr Shahana

10.	Sankara Eye Hospital, Varthur Main Road, Kundalahalli Gate Bengaluru Karnataka - 560037	Ethics Committee Institutional Review Board ECR/705/INST/KA/2015/RR-21	Dr Rajesh Ramanjulu
11.	Sankara Eye Hospital, Sathy Main Road, Sivananda Puram Coimbatore Tamil Nadu - 641035	ETHICS COMMITTEE -SANKARA EYE CARE INSTITUTIONS ECR/512/Inst/TN/2014/RR-20	Dr Prabhu Shanker M
12.	The Eye Foundation, 582-A, DB Road, RS Puram Coimbatore Tamil Nadu	The Eye Foundation Ethics Committee ECR/934/Inst/TN/2017/RR-20	Dr Jatinder Singh
13.	Narayana Nethralaya, 121-C Chord Road, 1st R Block, Rajaji Nagar, Bengaluru Karnataka -530010	NARAYANA NETHRALAYA ETHICS COMMITTEE ECR/187/Inst/Kar/2013/RR-19	Dr Naresh Kumar Yadav
14.	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 ECR/361/Inst/MH/2013/RR-24	Dr Nilesh Balaji Giri
15.	Agrawal Hospital, Malviya Industrial Area Jaipur Rajasthan - 302017	Somani Hospital Ethics Committee ECR/1531/INST/RJ/2021	Dr Vishal Agrawal
16.	L V Prasad Eye Institute, MTC Campus, Patia, Bhubaneswar Bhubaneswar Orissa - 751024	Institutional Ethics Committee ECR/496/Inst/OR/2013/RR-19	Dr Umesh Chandra Behera
17.	Aravind Eye Hospital, Avinashi Road Coimbatore Tamil Nadu- 641014	INSTITUTIONAL HUMAN ETHICS COMMITTEE ECR/252/Inst/TN/2013/RR-19	Dr George J Manayath
18.	Advanced Retina Care, Cross Road BRTS Stop, 404, 405, AAGAM Avenue Near Adani Gas Station and AAGAM flats On Sabarmati, Visat Road, Opp. Motera, Motera Ahmedabad Gujarat - 380005	Riddhi Medical Nursing Home IEC ECR/886/Inst/GJ/2016/RR-24	Dr Ruchi Mehta
19.	KAR Vision Eye Hospital, 10, Satyanagar, Janpath, Bhubaneswar BhubaneswarOrissa - 751007	Kar Vision Institutional Ethics Committee ECR/1630/Inst/OD/2021	Dr Sanghamitra Kanungo
20.	Shroff Eye Hospital and Lasikcentre, 222, S V Road, Bandra West Mumbai Maharashtra -400050	SHROFF EYE HOSPITAL AND VISION RESEARCH ECR/873/Inst/MH/2016/RR-20	Dr Rahul Shroff

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