



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/24/000156**

To,

M/s Syneos Health India Pvt Ltd,  
4th Floor Block -2, DLF Downtown, Commercial Site,  
Block-V, DLF City, Phase III Sector 25A,  
Gurugram DLF Qe Gurugram (India) - 122002

Sir,

With reference to your application No. GCT/CT04/FF/2024/46889 dated 20-Dec-2024; please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3, Multicenter, Prospective, Randomized, Double-Masked, Parallel-Group Study of EYP-1901, a Tyrosine Kinase Inhibitor (TKI), Compared to Aflibercept in Subjects with Wet AMD” Protocol no. EYP-1901-302, Amendment 1, dated 29-Aug-2024 with a total of up-to 100 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:-

- (i) **Human biological samples i.e. Human blood (whole), plasma, serum and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (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 Licencing 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 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;
- (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 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;
- (ix) 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;
- (x) 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;
- (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 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;
- (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 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;
- (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 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvii) 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;
- (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;
- (xix) 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;
- (xx) 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,

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

**FORM CT-06**  
(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 Syneos Health India Pvt Ltd, 4th Floor Block - 2, DLF Downtown, Commercial Site, Block-V, DLF City, Phase III Sector 25A, Gurugram DLF Qe Gurugram (India) - 122002 Telephone No.: 9811362577 FAX: 020-30569158 E-Mail : SM\_INVENTIV\_REGULATORY@SYNEOSHEALTH.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. EYP-1901-302, Amendment 1, dated 29-Aug-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 \_\_\_\_\_

(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:

<b>Names of the new drug or investigational new drug</b>	Vorolanib
<b>Therapeutic class:</b>	Tyrosine Kinase Inhibitor
<b>Dosage form:</b>	Insert
<b>Composition:</b>	Vorolanib =1343.0000 microgram per Insert In House Specification Active
<b>Indications:</b>	Treatment of Wet Age Related Macular Degeneration wAMD

**Annexure:**

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Narayana Nethralaya, Narayana Nethralaya #121/C, Chord Raod, Rajajinagar, 1 <sup>st</sup> "R" Block, Bnagalore Karnataka - 560010	Narayana Nethralaya Ethics Committee, Narayana Nethralaya 121/C, Chord Road, 1st R Block, Rajajinagar, Bangalore-560010, Karnataka, India  ECR/187/Inst/Kar/2013 RR-19	Santosh Gopi Krishna
2.	All India Institute of Medical Sciences, Ethics Committee, AllIndia Institute of Medical Sciences, Room No. 102, 1stFloor, Old O.T. Block, Ansari Nagar, New Delhi Delhi -110029	Institute Ethics Committee All India Institute Of Medical Scie Old OT Block, Room No-102, AIIMS Hospital, Ansari Nagar, New Delhi-110029, India.  ECR/538/Inst/DL/2014/RR-20	Dr Rajpal Vohra
3.	K B Haji Bachooali Charitable Ophthalmic and E N T Hospital, Free Ophthalmic Hospitals Societys 58 60 Jehangir Merwanji Street Parel Mumbai Maharashtra - 400012	FOHS KBHB Charitable Ophthalmic and ENT Hospital 58/60, Jehangir Merwanji Street, Parel, Mumbai Mumbai City Maharashtra  ECR/919/Inst/MH/2017/RR-22	Dr. Anand Subramanyam
4.	Shanti Saroj Netralay A NGAikwad, 901 902 BesideSundar Nagar Anand Nursing home road off Sangli Miraj Rd Miraj Mumbai Maharashtra -416410	IEC-Saishwari Clinic -Hospital for Mental Health Saishwari Clinic -Hospital for Mental Health Yashwant Co Op Housing Society Sangli Road, Miraj Sangli Maharashtra - 416410 India  ECR/1245/Inst/MH/2019/RR-24	Dr. Sharad Bhomaj
5.	Nethra Eye hospital, No 8Poojary Layout 80 Ft Road R MV 2nd Stage Bangaluru Karnataka - 560094	PRANAV DIABETES CENTER ETHICS57/1, Nanda Complex Ramamurthy Nagar Main Road Banaswadi, Bangalore Urban Karnataka-560043  ECR/1217/Inst/KA/2019/RR-22	Dr. SRIBHARGAVA NATESH
6.	Shroff Eye Hospital and Vision Research Centre, 222 S V Road Bandra West Mumbai Maharashtra - 400050	Shroff Eye Hospital Ethics Committee 222, S. V. Road, Bandra West, Mumbai - 400050.  ECR/873/Inst/MH/2016/RR-20	Dr Rahul Shroff

7.	Netrodaya the Eye City Hospital., Arazi Number 651652 NH 2 Toll Plaza Dafi Varanasi Uttar Pradesh - 221008	Netrodaya Institutional Ethics Committee Netrodaya The Eye City LLP Arazi No 651 And 652 Near Dafi Toll Plaza, Dafi Varanasi Varanasi Uttar Pradesh - 221008 India  ECR/1832/Inst/UP/2023	Dr Abhishek Dixit
8.	Netralayam the Super Specialty Eye Care Centre, Shree Tower II RAA 36 Raghunathpur VIP Road Kolkata West Bengal - 700059	Netralayam Ethics Committee Shree Tower II, RAA 36, Raghunathpur, VIP Road, Kolkata-700059, West Bengal, India.  ECR/1019/Inst/WB/2017/RR-21	Dr. Rupak Kanti Biswas
9.	Aravind Medical Research, Foundation Block No 1 Anna Nagar Madurai Tamil Nadu - 625020	Institutional Ethics Committee, (AEH) Aravind Medical Research Foundation Block, No. 1, Anna Nagar, Madurai, Tamil Nadu, India  ECR/182/Inst/TN/2013/RR-19	Dr Naresh Babu Kannan
10.	Post Graduate Institute of Medical Education and Research, Sector 12 Punjab Chandigarh - 160012	IEC, Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor P.N Chuttani Block Chandigarh Chandigarh – 160012, India  ECR/25/Inst/CH/2013/RR-20	Dr Mohit Dogra

\*\*\*\*\*