सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road,
New Delhi – 110002
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/22/000049

To

M/s. IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road, Kadubeesanahalli,
Bengaluru – 560103, Karnataka, India.

Sir,

With reference to your SUGAM application no. GCT/CT04/FF/2022/32118 (GCT/49/22) dated 17-MAY-2022, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3 part of clinical trial titled," **A Randomized, Double-masked, Parallel-group, Multicenter, Clinical Study to Evaluate the Efficacy and Safety of AVT06 Compared with EU-Eylea® in Subjects with Neovascular (wet) Age-related Macular Degeneration (ALVOEYE)" Protocol Number: AVT06-GL-C01, Amendment 1.0, Version 2.0, dated 21-DEC-2021** with a total of up to 63 subjects 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, specifically that: -

1) **if the subject develop CNV in the fellow eye, then it should be managed as per the standard of care and the cost of the same should be borne by the Sponsor;**
2) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Institutional 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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba4152525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.07.18 [illegible]

(Dr. V. G. Somani)
Drugs Controller General (India) &
Central Licencing Authority

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. IQVIA RDS (India) Private Limited, Omega Embassy TechSquare, Marathahalli-Sarjapur Outer Ring Road Kadubeesanahalli, Bengaluru–560103, Karnataka, India** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. AVT06-GL-C01, Amendment 1.0, Version 2.0, dated 21-DEC-2021** 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 _____

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba4152252sffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.10.31 [illegible]

(Dr. V. G. Somani)
Drugs Controller General (India) &
Central Licensing Authority

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	AVT06 (Aflibercept)
Therapeutic class:	Recombinant Fc Fusion Protein
Dosage form:	Solution for injection (IVT)
Composition:	Aflibercept = 40.00 mg/ml (in house specification) Active
Indication:	Neovascular (wet) Age-related Macular Degeneration

Annexure:

Details of clinical trial site:

S.No.	Names and address of clinical trial site	Ethics committee details	Name of Investigator
1.	Advanced Eye Centre, Post Graduate Institute of Medical Education and Research, Madhya Marg, Sector 12, Chandigarh - 160012	Institutional Ethics Committee, Room No. 6006, 6th floor, PN Chuttani Block, Post Graduate Institute of Medical Education and Research, Sector 12 Chandigarh - 160012	Dr. Reema Bansal
2.	Dept. of Ophthalmology, King George's Medical University, ShahMina Road, Chowk, Lucknow – 226003, Uttar Pradesh	Institutional Ethics Committee King George's Medical College, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow –226003, Uttar Pradesh	Dr. Sandeep Saxena
3.	Department of Ophthalmology, Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta. Waghodia, Vadodara-391760, Gujarat	Sumandeep Vidyapeeth Institutional Ethics Committee, Research Cell, 2nd Floor, Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta. Waghodia, Vadodara-391760, Gujarat	Dr. Punit Kumar Singh
4.	Shivam Retina Clinic and Eye Hospital, HG-1 A, ITC Building, Majura Gate, Ring Road, Surat - 395001, Gujarat	Unity Hospital Ethics Committee, Unity Trauma Center and ICU, N-4 Janki Park Society, Aai Mata Road, Paravat Patiya, Surat Gujarat – 395010	Dr Shobhana Mange
5.	Government Medical College and Sir Takhtasinhji Hospital, Bhavnagar-364001, Gujarat	Ethics Committee Government College, Bhavnagar, near St. Bus Stand, Jail Road, Bhavnagar-364001, Gujarat	Dr. Neepa R Gohil
6.	Pagarav Hospital & ICU, Clinical Research Department, 3rd floor, Plot No. 512/1, Sector-23, Nr. G-6 Circle, Opp. SBI, Gandhinagar-382023, Gujarat	Pagarav Ethics Committee, Pagarav Hospital & ICU, Room No. 10, Basement, Plot No. 512/1, Nr. G-6 Circle, Opp. SBI, Sector-23, Gandhinagar-382023, Gujarat	Dr. Urmil Mahesh Shah
7.	Netralaya Super Speciality Eye Hospital, 1st Floor, Kay Dee House, Above Union Bank of India, Opp. Gujarat Gas, Parimal Garden Cross Road, CG Road Ahmedabad-380006, Gujarat	Ethics Committee of Care Institute of Medical Sciences, CIMS Hospital Pvt. Ltd., Near Shukan Mall, 380060, Gujarat	Dr. Parth Jagdishkumar Rana

8.	Shroff Eye Hospital and Vision Research Centre, 222, S.V. Road, Bandra(W) Mumbai- 400050, Maharashtra	Shroff Eye Hospital Ethics Committee, Shroff Eye Hospital and Vision Research Centre, 222, S.V. Road, Bandra(W), Mumbai-400050, Maharashtra	Dr Rahul Ashok Shroff
9.	Department of Ophthalmology, B.J. Govt. Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station Pune-411001, Maharashtra	IEC of B.J .G.M. C And Sassoon General Hospital, B.J.G.M. College and Sassoon Government Hospital, , Sassoon Road, Station Road, Pune Maharashtra - 411001	Dr Usha Subhash Nikumbh
10.	Natasha Eye Care Hospital, Department of Ophthalmology, Retina Division, Room #01, Shiva Sai Lane, Building A Sai Saheb, Pimple Saudagar, Pune-411027, Maharashtra	Niramaya Hospital Ethics Committee, Niramaya Hospitals Pvt. Ltd., Survey No. 4742, Behind Jaihind Petrol Pump, Next to Chinchwad Post office, Chinchwad Haveli, Pune, Maharashtra-411019	Dr. Kishore Tulsidas Pahuja
11.	Dr. Virendra Laser Phaco Surgery Centre, First Floor, Room No. 108, Tonk Phatak, Tonk Road, Gandhi Nagar, Jaipur-302015, Rajasthan	Institutional Ethics Committee Dr. Virendra Laser Phaco Surgery Centre, Tonk Phatak Tonk Road, Gandhi Nagar, Jaipur-302015, Rajasthan	Dr Virendra Agrawal
12.	L V Prasad Eye Institute, Kallam Anji Reddy Campus, L V Prasad Marg, Road No. 02, Banjara Hills, Hyderabad-500034, Telangana	Ethics Committee L V Prasad Eye Institute, Kallam Anji Reddy Campus, L V Prasad Marg, Road No. 02, Banjara Hills, Hyderabad-500034, Telangana	Dr. Dave Vivek Pravin
13.	Aravind Eye Hospital, Avinashi Road, Civil Aerodrome Post, Kalapatti, Coimbatore Corporation East Coimbatore- 641014, Tamil Nadu	Institutional Human Ethics Committee, PSG institute of Medical Sciences and Research, Post Box no. 1674, Avinashi Road, Peelamedu, Coimbatore, Tamil Nadu 641004	Dr Rodney John Morris
14.	The Eye Foundation, 582 A, D.B. Road, R S Puram, Coimbatore-641002, Tamil Nadu	The Ethics Committee of the Eye Foundation, The Eye Foundation, 582 A, D.B. Road, Coimbatore Tamil Nadu – 641002	Dr. Jatinder Singh
15.	Sankara Eye Hospital, (Sri Kanchi Kamakoti Medical Trust) Sathy Road, Sivanandapuram Coimbatore - 641035, Tamil Nadu	Institutional Ethics Committee, Sankara Eye Care Institutions, Sathy Road, Sivanandapuram, Sankara Eye Hospital, Sathy Road, Sivanandapuram Coimbatore - 641035, Tamil Nadu	Dr Prabhu Shankar Mahalingam
16.	Dr. Agarwal's Eye Hospital, No. 10/1/1-5, land Mark Towers, South Bypass, opp to BSNL, Vannarpet, Tirunelveli- 627003, Tamil Nadu	Dr. Agarwal's Eye Hospital Institutional Review Board, Dr. Agarwal's Eye Hospital, No. 10/1/1-5, land Mark Towers, South Bypass, opp to BSNL, Vannarpet, Tirunelveli- 627003, Tamil Nadu	Dr. Lional Raj D

17.	Narayana Nethralaya, 121/C, Chord Road, 1st R Block, Rajaji Nagar , Bnagalore-560010, Karnataka	Narayana Nethralaya Ethics Committee, Narayana Nethralaya, 121/C, Chord Road, 1st R Block, Rajaji Nagar , Bnagalore-560010, Karnataka	Dr. Chaitra Jayadev
18.	JPM Rotary Eye Hospital, CDA. Sector VI, Market Nagar, Cuttack-753014, Orissa	Institutional Ethics Committee JPM Rotary Eye Hospital, JPM Rotary Eye Hospital, CDA. Sector VI, Market Nagar Cuttack, Orissa – 753014	Dr. Santosh Kumar Mahapatra
19.	Sri Sankaradeva Nethralaya, Vitreo Retina Department, 96, Basistha Road, Guwahati – 781028, Assam	Sri Sanakaradeva Nethralaya Institutional Ethics Committee (SSNIEC), 96, Basistha Road, Guwahati – 781028, Assam	Dr. Manabjyoti Barman

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