



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/20/000165

Dated 01-Mar-2021

To,

M/s Enzene Biosciences Ltd.,
Pune, Plot No. 165/1/26, T-Block MIDC,
Bhosari, Pune Pimpri Chinchwad (India) - 411026

Subject: Application for grant of permission to conduct clinical trial entitled – “A Comparative, Double-Blind, Randomized, Multicenter, Phase III study to compare the safety & efficacy of ENZ105 of Enzene Biosciences Ltd. with Innovator Ranibizumab in subjects with Neovascular (Wet) Age related Macular Degeneration (AMD)” vide Protocol No.: ALK21/ENZ105-RANI1, Version 2.0, Dated 23/Nov/2020 - regarding

Ref.: Your Application No. BIO/CT04/FF/2020/22097 dated 08-Oct-2020

Sir,

With reference to your Application No.: BIO/CT04/FF/2020/22097 dated 08-Oct-2020, 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) Submit satisfactory COA (as per ICH requirements) of MCB batches used for manufacturing of Clinical Trial batches, before initiation of the Clinical 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;
- (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 authorised 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.

Yours faithfully,

VENUGOPAL
GIRDHARILAL
SOMANI

Digitally signed by VENUGOPAL
GIRDHARILAL SOMANI
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ou=CDSCO DGHS, postalCode=431401,
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(Dr. V.G. Somani)

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 Licencing Authority hereby permits M/s Enzene Biosciences Ltd., Pune, Plot No. 165/1/26, T-Block MIDC, Bhosari, Pune Pimpri Chinchwad (India) - 411026 to conduct clinical trial of the new drug or investigational new drug study titled "A Comparative, Double-Blind, Randomized, Multicenter, Phase III study to compare the safety & efficacy of ENZ105 of Enzene Biosciences Ltd. with Innovator Ranibizumab in subjects with Neovascular (Wet) Age related Macular Degeneration (AMD)" vide Protocol No.: ALK21/ENZ105-RANI1, Version 2.0, Dated 23/Nov/2020 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: 01-Mar-2021

**VENUGOPAL
GIRDHARILA
L SOMANI**

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

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Ranibizumab (r-DNA origin)
Therapeutic class:	VEGF Antagonist
Dosage form:	Solution for injection (Liquid)
Composition:	Ranibizumab Drug Substance =10 mg/ml In House (Active) Polysorbate 20 =0.1 mg/ml B.P.,E.P.,J.P. (Inactive) L-Histidine =0.321 mg/ml U.S.P.,E.P.,J.P. (Inactive) L-Histidine hydrochloride monohydrate =1.662 mg/ml B.P.,E.P. (Inactive) Trehalose dihydrate =100 mg/ml U.S.P. (Inactive)
Indications:	Neovascular 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	Lifepoint Multispeciality Hospital, Department of Ophthalmology, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji Wakad, Pune- 411057, Maharashtra, India	LPR Ethics Committee, Lifepoint Multispeciality Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji Wakad, Pune- 411057, Maharashtra, India EC Reg. No.: ECR/751/INST/MH/2015/RR-18	Dr. Anmol Naik
2	Department of Ophthalmology, Sir Ganga Ram Hospital, SGRH Marg, Old Rajinder Nagar, New Delhi- 110060, Delhi, India	Sir Ganga Ram Ethics Committee, Room no. 1496, 4th floor, Old Rajinder Nagar, New Delhi- 110060 EC Reg. No.: ECR/20/INST/DL/2013/RR-2019	Dr Tinku Bali Razdan
3	Aakash Healthcare Pvt. Ltd., Hospital Plot, Road no. 201, Sector-3, Dwarka, New Delhi- 110075	Aakash Healthcare Super Speciality Hospital Institutional Ethics Committee, Hospital Plot, Road no. 201, Sector-3, Dwarka, New Delhi- 110075 EC Reg. No.: ECR/1265/INST/DL/2019	Dr Prashant Chaudhary
4	Ishwar Institute of Healthcare, department of Ophthalmology, Ishwar heights, 1st floor, plot no. 7, Gut no. 6/1, Beside Punjabi Bhawan, Padegaon, Aurangabad- 431002, Maharashtra	Ethics Committee of Ishwar Institute of Health care, Ishwar heights, 3rd floor, plot no. 7, Gut no. 6/1, Beside Punjabi Bhawan, Padegaon, Aurangabad- 431002, Maharashtra EC Reg. No.: ECR/988/INST/MH/2017/RR-20	Dr Abhijit Gore
5	Heritage Institute of Medical Sciences, NH2, GT Road Bypass, Bhadwar, Varanasi- 221311, Uttar Pradesh	Institutional Ethics Committee, Heritage Institute of Medical Sciences, NH2, GT Road Bypass, Bhadwar, Varanasi- 221311, Uttar Pradesh EC Reg. No.: ECR/1071/INST/UP/2018	Dr. Shrikant
6	Department of Ophthalmology, 2nd floor, New OPD Building, Lokmanya Tilak Municipal Medical College and General Hospital, Dr. Ambedkar	Institutional Ethics Committee Lokmanya Tilak, Dr. Babasaheb Ambedkar Road, Sion (West), Mumbai- 400022 EC Reg. No.: ECR/266/Lokmanya/Inst/MH/2013/RR-19	Dr. Chhaya Shinde

	Road, Sion, Mumbai- 400022		
7	Department of Ophthalmology, Ground Floor, Ophthalmology block, K R Hospital, Mysore Medical College & Research Institute, Irwin Road, Mysore-570001	Institutional Ethics committee, Mysore Medical College and Research Institute and Associate Hospitals, Mysore Medical College & Research Institute, Irwin Road, Mysore- 570001, Karnataka EC Reg. No.: ECR/134/INST/KA/2013/RR-2019	Dr. K Sathish
8	JLN Medical college and attached hospital, opp. Patel stadium, Rajasthan 305001	Institutional Ethics committee, Jawahar Lal Nehru Medical College & Attached Hospitals, opp. Patel stadium, Rajasthan 305001 EC Reg. No.: ECR/1156/INST/RJ/2018	Dr. Rakesh Porwal
9	Seth G.S. Medical College and KEM Hospital, Ward No 42, 10th Floor, Department of Haematology, Acharya Donde Marg, Parel, Mumbai 400012	Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai 400012 EC Reg. No.: ECR/417/Inst/MH/2013/RR-16	Dr Sheela Kerkar
10	Department of Ophthalmology, Sri Ramachandra Institute of Higher Education and Research, Clinical Research Division, Dental college basement, No. 1, Ramachandra nagar, Porur, Chennai- 600116	Institutional Ethics Committee-SRIHER, Sri Ramachandra Institute of Higher Education and Research, No. 1, Ramachandra nagar, Porur, Chennai-600116 EC Reg. No.: ECR/203/INST/TN/2013/RR-19	Dr. Radha Annamalai
11	Adichunchanagiri Hospital & Research Centre, B G Nagara, Nagamanagala, Mandya, Karnataka- 571448	Institutional Ethics Committee, Adichunchanagiri Hospital & Research Centre, B G Nagara, Nagamanagala, Mandya, Karnataka- 571448 EC Reg. No.: ECR/659/INST/KA/2018	Dr. H T Venkate Gowda
12	Nirmal Hospital Pvt. Ltd., Ring Road, Surat- 395002	Nirmal Hospital Ethics Committee, 2/1423-8-6 Sagarampura Ring Road, Near Centre Point, Surat- 395002 EC Reg. No.: ECR/390/INST/GJ/2013/RR-19	Dr. Bhavin Zariwala
13	Department of Ophthalmology, Dr BR Ambedkar Medical College and Hospital, K G Halli, Bangalore- 560045	Institutional Ethics Committee, Dr Dr. BR Ambedkar Medical College and Hospital, K G Halli, Bangalore- 560045 EC Reg. No.: ECR/508/INST/K/2014/RR-17	Dr. Rani Sujatha
14	Department of Ophthalmology, Jipmer Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006.	Institutional Ethics Committee for human studies, Jipmer Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006 EC Reg. No.: ECR/342/Inst/PY/2013/RR-19	Dr Amit Kumar Deb
15	M & J Western Regional Institute of Ophthalmology, Government of Eye Hospital, Manjushree Mill Compound, Asarwa, Ahmedabad-380016	The Institutional Ethics Committee, B J Medical College and Civil Hospital, Asarwa, Ahmedabad- 380016 EC Reg. No.: ECR/72/INST/GJ/2013/RR-19	Dr Somesh Agarwal

16	Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS Campus Temple, Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Institute Ethics Committee, All India Institute of Medical Sciences (AIIMS), AIIMS Campus Temple, Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029 EC Reg. No.: ECR/538/INST/DL/2014/R-17	Dr. Vinod Agarwal
17	Aditya Jyot Eye Hospital, 153, Road No.9, Major Parmeshwaran Road, Wadala (West), Mumbai-400031, Maharashtra, India.	Aditya Jyot Eye Hospital Ethics Committee, Aditya Jyot Eye Hospital. 2nd floor, Plot no. 153, Road No.9, Major Parmeshwaran Road, Wadala (West), Mumbai-400031, Maharashtra, India. EC Reg. No.: ECR/332/INST/MH/2013/R-16	Dr. S Natarajan

