



File No. BIO/CT/24/000084

Dated: 29-11-2024

To,

M/s Gennova Biopharmaceuticals Limited,
P-1 & P-2, ITBT Park,
Phase -II MIDC Hinjawadi (India) – 411057

Subject: Application for grant of permission to conduct Phase III clinical trial entitled – “A Phase III Prospective, Randomized, Open-labelled, Blinded endpoint(PROBE), Multi-centric, Parallel Group, Non-inferiority Study to compare the Efficacy and Safety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration (PROMISES Study)” as per Protocol No. GBL1204/2024/01, Version 2.0, 18-Sep-2024-regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/44244 dated 19.07.2024 and E receipt- 50321 dated 20.08.2024-reg

Sir,

With reference to your application No BIO/CT04/FF/2024/44244 dated 19.07.2024, 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) DSMB report on the safety of first 50 patients and further on regular basis shall be submitted to CDSCO forthwith.**
- (II) CSR shall be submitted to this office after completion of trial.**
- (III) 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
- (IV) 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;
- (V) 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;
- (VI) 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;

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 Genova Biopharmaceuticals Limited, P-1 & P-2, ITBT Park, Phase -II MIDC Hinjawadi (India) – 411057 to conduct Phase III clinical trial titled- “A Phase III Prospective, Randomized, Open-labelled, Blinded endpoint(PROBE), Multi-centric, Parallel Group, Non-inferiority Study to compare the Efficacy and Safety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration (PROMISES Study)” as per Protocol No. GBL1204/2024/01, Version 2.0, 18-Sep-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.
4. It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 29.11.2024

**RAJEEV SINGH
RAGHUVANSHI**

Digitally signed by 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:	Bevacizumab Injection 1.25mg PFS (r-DNA origin)	
Therapeutic class	VEGF inhibitor	
Dosage form:	One pre-filled syringe contains 3.5 mg bevacizumab in 140 microlitres (25 mg/ml) Delivers a single dose of 1.25 mg/0.05 ml	
Composition:	Each PFS contains:	
	Name of Ingredients	Quantity per PFS
	Bevacizumab, In-house	3.5 mg
	Monobasic sodium phosphate monohydrate I.P./B.P./Ph.Eur.	0.812mg
	Sodium dihydrogen phosphate monohydrate I.P./B.P./Ph. Eur	0.812mg
	Monosodium phosphate monohydrate I.P./B.P./Ph. Eur	0.812mg
	Anhydrous Disodium Hydrogen Phosphate BP / Ph. Eur.	0.168mg
	Trehalose Dihydrate BP / Ph. Eur. / USP	8.400mg
	Water for Injections I.P. / BP / Ph. Eur. / USP	q.s.to0.140ml
Indications:	Wet Age Related Macular Degeneration (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.	All India Institute of Medical Sciences (AIIMS) New Delhi	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi – 110029 EC reg No. ECR/538/Inst/DL/2014/RR-20	Dr. Vinod Kumar
2.	KR Hospital, Mysore Medical College and Research Institute. Mysore	IEC-MMC and RI and Associated Hospital Mysore Medical College and Research Institute, Irwin Road Mysore, Karnataka – 570001 EC reg No. ECR/134/Inst/KA/2013/RR-19	Dr. Satish K
3.	Dr. D.Y. Patil Medical College, Hospital And Research Centre, Pune	Ethics Committee – Dr D Y Patil Vidyapeeth Dr D Y Patil Vidyapeeth , Sant Tukaram Nagar, Pimpri, Pune, Maharashtra– 411018	Dr. Nilesh Balaji Giri

		EC Reg No. ECR/361/Inst/MH/2013/RR-19	
4.	Nandadeep Eye Hospital, Sangli	EC Saishwari Clinic -Hospital For Mental Health Saishwari Clinic - Hospital For Mental Health Yashwant Co Op Housing Society Sangli Road, Miraj, Maharashtra – 416410 EC Reg No. ECR/1245/Inst/MH/2019	Dr. Sourabh Dileep Patwardhan
5.	Shree Aurobindo Nethralaya, Raipur	Ethics Committee, Sanjeevani Cancer Hospital Sanjeevani CBCC USA, Cancer Hospital Front of Jain Mandir Dawada Colony Pachpedi Naka Raipur Chhattishgarh –492001 EC Reg No. ECR /818/Inst/CG/2016/RR-19	Dr. Moneesh Saxena
6.	GSVM Medical College, Kanpur	Ethics Committee, GSVM Medical College Kanpur Ethics Committee GSVM Medical College Kanpur Swaroop Nagar, Kanpur, Uttar Pradesh, – 208002 EC reg No. ECR/680/Inst/UP/2014/RR-20	Dr. Shalini Mohan
7.	NRS Medical College, Kolkata	Institutional Ethics Committee NRS Medical College N.R.S. Medical College and Hospital, 138, A.J.C Bose Road Kolkata, West Bengal – 700014 EC Reg No. ECR/609/Inst/WB/2014/RR-20	Dr. Uday Aditya Mukhopadhyay
8.	Rajendra Institute of Medical Science (RIMS) Ranchi	Institutional Ethics Committee, RIMS, Ranchi Rajendra Institute of Medical Sciences, 4th Floor, Administrative Building Bariatu, Ranchi, Jharkhand – 834009 EC Reg no. ECR/769/Inst/JH/2015/RR-21	Dr. Sunil Kumar
9.	Government Eye Hospital, M & J Institute of Ophthalmology, Ahmedabad	The Institutional Ethics Committee B.J Medical College & Civil Hospital, Ahmedabad, Gujrat – 380016 EC reg no. ECR/72/Inst/GJ/2023/RR-2019	Dr. Gonsai Jigneshgiri Yashvantgiri

10.	Minto Ophthalmic Hospital, RIO, BMCRI, Bangalore	Ethics Committee of BMCRI Ethics Committee of BMCRI Bangalore Medical College And Research Institute, Fort K R Road Bengaluru, Karnataka – 560002 EC Reg No. ECR/302/Inst/KA/2013/RR-20	Dr. Shashidhar S
11.	Lotus Eye Hospital and Institute, Coimbatore	Institutional Human Ethics Committee PSG Institute Of Medical Science & Research, Post box no. 1674, Avinashi road, Peelamedu, Coimbatore, Tamil Nadu– 641004 EC Reg No. ECR /252/Inst/TN/2013/RR-19	Dr. Ashish Sharma
12.	Dhiraj Hospital, Sumandeep Vidyapeeth Deemed to Be University, Vadodara	Institutional Ethics Committee, SV Sumandeep Vidyapeeth at And Post Pipariya, Vadodara Gujarat– 391760 EC Reg No. ECR152/Inst/GJ/2013/RR-19	Dr. Punit Kumar Singh
13.	All India Institute of Medical Sciences (AIIMS), Bhubaneswar	Institutional Ethics Committee, AIIMS Bhubaneswar All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar Sijua P/O Patrapada Bhubaneswar, Khordha Orissa – 751019 EC reg no. ECR /534/Inst/OD/2014/RR-20	Dr. Sucheta Parija
14.	All India Institute of Medical Sciences (AIIMS), Raipur	Institutional Ethics Committee AIIMS Raipur Room No. 2103, 2nd Floor South Wing Medical College Complex, Gate No. 5 All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, Chhattisgarh – 492099 EC Reg No. ECR /714/Inst/CT/2015/RR-21	Dr. Vijaya Sahu
15.	Shanti Saroj Netralaya, Sangli	IEC Saishwari Clinic -Hospital For Mental Health Saishwari Clinic -Hospital For Mental Health Yashwant Co Op Housing Society Sangli Road, Miraj, Maharashtra – 416410 EC Reg no. ECR/1245/Inst/MH/2019	Dr. Sharad Bhomaj
16.	Modern Eye Clinic Nashik	Shree Institutional Ethics Committee Dhadiwal Hospital In Coalitation with Shreeji Health Opp New CBS Trimbak Road Nashik, Maharashtra – 422002 EC Reg No. ECR/1149/Inst/MH/2018 /RR- 21	Dr. Rohit Sanjay Laul

17.	PBMA's H.V Desai Eye Hospital, Pune	Institutional Ethics Committee PBMA's H. V. Desai Eye Hospital S. No. 93 Tarawade Vasti, Mohammedwadi Road Hadapsar Pune, Maharashtra – 411060 EC Reg No. ECR/234/Inst/MH/2013/RR-22	Dr. Rashmi Kashikar
18.	SGS Super Speciality Hospital, Gandhinagar	Health1 super speciality hospital EC Health 1 Super Speciality Hospital Block C ,GF To 8 Floor, Shilaj 23/73, On S.P.Ring Road, Near Shilaj Circle, Shilaj. Ahmedabad Ahmedabad Gujarat – 380059 EC Reg No. ECR/1666/Inst/GJ/2022	Dr. Shukla Chaitanya Kireetbhai
19.	Advanced Eye Centre Post Graduate Institute of Medical Education and Research, Chandigarh, 160012	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor P N Chuttani Block Chandigarh– 160012 EC Reg No. ECR /25/Inst/CH/2013/RR-20	Dr. Vishali Gupta
20.	Dr. Agarwals eye hospital with Prabhu desai eye clinic, S.No. 32/1/1, Next to sweekar, Pune -411004, Maharashtra.	Institutional ethics committee, Lokmanya Medical Research Centre, 314/B Telco Road, Chinchwad, Pune 411033 EC Registration No: ECR/175/Inst/MH/2013/RR-19	Dr. Nitin Govind Prabhudesai
21.	Department of Ophthalmology, S.P. Medical College & A.G of Hospitals, Bikaner - 334001, Rajasthan.	Ethics committee S.P. Medical College, Pawanpuri, Bikaner- 334003 EC Registration No: ECR/27/SP/Inst/RJ/2013/RR- 19	Dr. Shilpi Kochar
22.	L V Prasad Eye Institute, Kallam Anji Reddy Campus, L.V Prasad Marg, Banjara Hills, Road No: 2, Hyderabad-500034. Telangana.	Ethics Committee, L V Prasad Eye Institute, 5th 'Floor, GPR Building, L V Prasad Eye Institute, Kallam Anji Reddy Campus, L V Prasad Marg, Banjara Hills, Road No: 2, Hyderabad-500034, Telangana, EC Registration No: ECR/468/Inst./AP/2013 /RR-19	Dr. Nikitha Reddy Gurram