



सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
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File No. BIO/CT/23/000124

Dated: 26-04-2024

To,

M/s. Enzene Biosciences Ltd.,
Plot no A 22, A/1/2 Chakan Industrial Area, Phase 2,
Khalumbre Chakan, Pune (India) – 410501

Subject: Application for grant of permission to conduct clinical trial entitled – "A prospective, multicenter, Open labelled, Phase IV study to establish the safety & efficacy of biosimilar Bevacizumab of Enzene Biosciences Ltd. in Combination with Chemotherapy in Patients with Metastatic Colorectal Cancer" as per Protocol No. ALK33/ENZ137-BEV2 Version 1.0 dated 28.08.2023- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/38352 dated 27.09.2023

Sir,

With reference to your application No. BIO/CT04/FF/2023/38352 dated 27.09.2023, 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) 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
- (II) 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;
- (III) 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;
- (IV) 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;
- (V) 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.
- (VI) 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.

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. Enzene Biosciences Ltd., Plot no A 22, A/1/2 Chakan Industrial Area, Phase 2, Khalumbre Chakan, Pune (India) – 410501 to conduct clinical trial entitled "A prospective, multicenter, Open labelled, Phase IV study to establish the safety & efficacy of biosimilar Bevacizumab of Enzene Biosciences Ltd. in Combination with Chemotherapy in Patients with Metastatic Colorectal Cancer" as per Protocol No. ALK33/ENZ137-BEV2 Version 1.0 dated 28.08.2023 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: 26-Apr-2024

RAJEEV SINGH
(Dr. Rajeev Singh Raghuvanshi)
RAGHUVANSHI
Drugs Controller General (India)
Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c2769041015a06564fe67f54b765db1cb, cn=Dr. Rajeev Singh Raghuvanshi
SerialNumber=6377307094936968f8b0dca72D0E1EECEA1241126FA94FA5711274A19018
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Date: 2024.04.29 12:34:18 +05'30'

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

Names of the new drug or investigational new drug:	Bevacizumab 25mg/ml (r-DNA origin), concentrate for solution for infusion	
Therapeutic class	Anti VEGF	
Dosage form:	Bevacizumab drug product (Concentrate for Solution for infusion in Vial) is available in two different presentations 100mg/4mL and 400mg/16mL which are supplied in a USP type-I clear glass vial, stoppered with bromobutyl rubber stopper and sealed with aluminium Flip off seal	
Composition:	Each vial contains:	
	Name of Ingredients	Quantity mg/mL
	Bevacizumab Drug substance, In-house	25
	α,α -trehalose dehydrate EP	60
	Sodium phosphate (monobasic monohydrate) IP	5.8
	Sodium phosphate (dibasic, anhydrous) EP	1.2
	Polysorbate 20 IP	0.4
	Sodium hydroxide IP	q.s. to pH 6.2
	Water for Injection IP	q.s. to 1mL
Indications:	Bevacizumab in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum	

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik-422002	Manavata Clinical Research Institute Ethics Committee HCG Manavata Cancer Centre Behind Shivang Auto Mumbai Naka Nashik Maharashtra -422002 India EC Reg No. ECR/500/Inst/MH/2013/RR-20	Dr. Raj Nagarkar
2.	MNJ Institute Of Oncology & Regional Cancer Centre, Red Hills, Hyderabad-500004, Telangana	MNJIO & RCC Ethics Committee MNJ Institute of Oncology and RCC Lakdikapool Red Hills Hyderabad Hyderabad Telangana -500004 India EC Reg No. ECR/227/Inst/AP/2013/RR-19	Dr. P Radhika
3.	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar, 751019, Odisha	Institutional ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Dumduma, Bhubaneswar, Odisha-751019 EC Reg No.: ECR/537/Inst/OD/2014/RR-17	Dr. Deepak Kumar Das

4.	Kolhapur Cancer Centre Pvt. Ltd., R. S. No. 238, Opp. Mayur Petrol Pump, Gokul Shirgaon, Karveer, Kolhapur-416234	Kolhapur Cancer Centre Institutional Ethics Committee R.S.238, Opp. Mayur Petrol Pump, Gokul Shirgaon-416234 Kolhapur, Maharashtra, India. EC Reg. No.: ECR/523/Inst/MH/2014/RR-20	Dr. Nilesh Dhamne
5.	Spandana Oncology Centre Pvt Ltd, 28th main road, 9th Block, Jayanagar, Bangaluru, Karnataka 560069	BGS-Global Institute of Medical Sciences, Institutional ethics Committee, 67 BGS Health and Education City, Uttarahalli Road, Kengeri Bangalore-560060, India EC Reg No. ECR/1307/Inst/KA/2019	Dr. Satheesh T
6.	Nirmal Hospital Pvt Ltd, Ring Road, Surat-395002	Nirmal Hospital Ethics Committee, Nirmal hospital Pvt. Ltd. 2/1423-8-6 Sagrampura ring road, Near Centre Point Surat-395002, Gujrat EC Reg No. ECR/390/Inst/GJ/2013/RR-2019	Dr. Dhruv Mehta
7.	S.M.S. Medical College and Hospital, J.L.N. Marg, Jaipur-302004	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Rajasthan -302004 EC Reg No: ECR/26/Inst/RJ/2013/RR-19	Dr. Ravindra Singh Gothwal