

File No: BIO/CT/18/000042
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

To,

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

Subject: Permission for conducting a Phase III clinical trial titled "A prospective, multicenter, randomized, double blind study to compare efficacy and safety of ENZ110 (similar biologic of Romiplostim) versus innovator Romiplostim in patients with chronic immune thrombocytopenia (ITP)".

Reference:- Your Application No. BIO/Form44/FF/2018/8438 dated 12-JUN-2018 on the subject mentioned above

Sir,

This Directorate has no objection to your conducting subject mentioned study under the provisions of Drugs and Cosmetics Rules 122-DA and 122-DAC, under the supervision of the investigators mentioned below as per Protocol No.: ALK10/ENZ110-ROMI1 Version 1.0 dated 10.05.2018 submitted to this Directorate.

	Name of Investigator	Clinical Trial Site address	Name and Address of the Ethics Committee
	Dr Pankaj Tantia	S.P Medical College & A.G Hospitals, HRMC Cardiovascular Sciences & Research Centre Bikaner Rajasthan - 334001	Ethics Committee, S.P Medical College & A.G Hospitals, HRMC Cardiovascular Sciences & Research Centre Bikaner 334001 Registration No. ECR/27/SP/INST/RAJ/2013/RR 2016
	Dr SVSS Prasad	Apollo Hospitals, Apollo Hospitals (Apollo Health City) Jubilee Hills Hyderabad Andhra Pradesh - 500096	Ethics Committee- Apollo Hospitals Situated at Apollo Hospitals (Apollo Health City), Jubilee Hills, Hyderabad 500096, Andhra Pradesh, India Registration No. ECR/38/Inst/AP/2013/RR-2016
	Dr Raguveer Prabhu	Amrita Institute OF medical sciences and Research centre, AIMS, Ponekkara POM Kochi Kerala - 682041	Institutional Ethics Committee, Amrita Institute of Medical and Research Centre, AIMS – Ponekkara Post, Kochi, Kerala – 682 041 Registration No. ECR/129/Inst/KL/2013/RR-2016
	Dr Rayaz Ahmed	Rajiv Gandhi Cancer Institute and Research Centre , Sector-5 Rohini Delhi Delhi - 110085	Institutional Review Board, Rajiv Gandhi Cancer Institute and Research Centre Sector-5 Rohini Delhi-110085 Registration No. ECR/10/Inst/DL/2013/RR-2016
	Dr Prashantha B	Kasturba Hospital, The Chairman, Manipal University Ethics Committee, 7th Floor,	Institutional Ethics Committee, HR Department , Kasturba Hospital, Manipal-576704

		Kasturba Hospital, Attavar, Mangalore Karnataka -	Registration No. ECR/191/Inst/KL/2013/RR-2016
	Dr A K Tripathi	King George's Medical College, Administrative Block, King George's Medical University, Lucknow Uttar Pradesh - 226003	Institutional Ethics Committee, K.G. Medical University, B-3/11, Vishal Khand, Gomti Nagar, Lucknow, UP, INDIA Registration No. ECR/262/Inst/UP/2013/RR-2016
	Dr Namita Padwal	Lokmanya Tilak Municipal Medical College Building, 2nd floor, room No 17 Sion Mumbai -400022 Mumbai Tamil Nadu - 400022	Institutional Ethics Committee Lokmanya Tilak Municipal Medical College 2nd Floor, Room No. 17 Sion Mumbai-400022 Registration No. ECR/266/Inst/MH/2013/RR2016
	Dr Vikram Mathews	Christian Medical College, Research Office, First Floor, Carman Block, Christian Medical College, Vellore Tamil Nadu - 632002	Ethics Committee Silver, Research office, First Floor, Carman Block, Christian Medical College, Vellore 632002, Tamilnadu Registration No. ECR/326/Inst/TN/2013/RR - 2016

Licensing Authority as defined in clause (b) of Rule 21, issue permission for conduct of clinical trial, subject to the following conditions further, namely:-

(a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y annexed to these rules, Good Clinical Practice Guidelines for conduct of clinical trials in India and other applicable regulations;

(b) Approval of the Ethics Committee shall be obtained before initiation of the study;

(c) Clinical trial shall be registered at Clinical Trials Registry of India before enrolling the first patient for the study;

(d) Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

(e) Any report of serious adverse event occurring during clinical trial to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

(f) In case of an injury or death during the clinical trial to the subject of the clinical trial the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with Rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority;

(g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trials in India and other applicable regulations;

(h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites and the investigator shall allow officers authorized by the Central Drug Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of sponsor including their employees, subsidiaries and

branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs etc. related to clinical trials and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial;

(l) Submit complete report of clinical trials as per the approved protocol from the individual investigator duly signed by him along with his observations/remarks on the drug.

(j) Indicating the date of commencement and conclusion of the clinical trial at each center (in case the study is multicentric).

(k) The bulk drug to be used in the manufacturing of finished formulation intended to be used in the clinical trial and clinical trial batches of finished formulation shall be manufactured under GMP conditions using validated procedure and shall have ongoing stability programme.

(l) If the clinical trial batches are different from that of the primary batches for which data have been submitted, stability report for clinical trial batches are to be submitted as per Appendix IX of Schedule Y of Drugs and Cosmetic Rules for Drug substance and formulation along with Clinical study report.

It may kindly be noted that merely granting permission to conduct clinical trials 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.

It is informed that all the amendments to Rule 122DAA, inclusion of Rule 122DAB, compensation matters etc. that are appended to the Drugs & Cosmetics Act & Rule, vide GSR 53 (E) dated 30.01.2013 and in Part X-A, after Rule 122DAB, Rule 122 DAC vide GSR 63 (E) dated 01.02.2013 are mandatory and binding.

Yours faithfully,

S ESWARA
REDDY
(Dr. S. Eswara Reddy)
Drugs Controller General (I)

Digitally signed by
S ESWARA REDDY
Date: 2018.11.06
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