

File No: BIO/CT/19/000101
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan,
Kotla Road
New Delhi 110 002

To,

M/s Eris Lifesciences Limited,
7th Floor, Commerce House-IV, Nr. Prahlad Nagar,
100 Ft. Road, Ahmedabad– 380015, Gujarat

Subject: Application for grant of clinical trial permission to conduct “A Phase III, Randomized, Open-Label, Multicentre, Clinical Trial to evaluate the efficacy and safety of Recombinant Human Thrombopoietin (rhTPO) Injection compared with Romiplostim injection in Indian Patients with Immune Thrombocytopenia” as per Protocol Number.: CT-TPIAO-001-ITP-2019, Version No. 1.0, Dated 05 Dec 2019 under the D&C Act and Rules thereunder-Regarding

Ref: Your application no. BIO/CT04/FF/2019/17716 dated 11-DEC-2019
Sir,

Please refer to your application no. BIO/CT04/FF/2019/17716 dated 11-DEC-2019, received by this office on the above subject. Please find enclosed herewith permission to conduct Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same

Yours faithfully,

V G
SOMANI



Digitally signed by V.G. SOMANI
DN: cn=V.G. SOMANI, o=CENTRAL DRUGS
STANDARD CONTROL
ORGANIZATION,
2.5.4.20=1118906bcb091ed5df9ed4
0e20e84142222c0caab151120bee65
202885, email=V.G.SOMANI@CDSCO,
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(Dr. V.G. Somani)
Drugs Controller General (India)

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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 to M/s Eris Lifesciences Limited, 7th Floor, Commerce House-IV, Nr. Prahlad Nagar, 100 Ft. Road, Ahmedabad- 380015, Gujarat to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: CT-TPIAO-001-ITP-2019, Version No. 1.0, Dated 05 Dec 2019 in the below mentioned clinical trial sites.-

Details of new drug or investigational new drug:	
Name of the new drug or investigational new drug:	Recombinant Human Thrombopoietin Injection
Therapeutic class:	Anticancer
Dosage form:	Solution for infusion
Composition:	1. Recombinant human thrombopoietin 7500 U (Active substance), Human albumin solution Stabilizer 2.50 mg, Sodium chloride Isotonic agent 9.30 mg Water for injection Solvent Add to 1.0 ml 2. Recombinant human thrombopoietin 15000 U (Active substance), Human albumin solution Stabilizer 2.50 mg, Sodium chloride Isotonic agent 9.30 mg Water for injection Solvent Add to 1.0 ml
Indications:	Recombinant human thrombopoietin injection is indicated to treat patients with immune thrombocytopenia (ITP) whose platelet count below 20×10 ⁹ /L if he/she failed to corticosteroid (including patients whose initial treatment is invalid or whose initial treatment is effective but corticosteroid is invalid for the recurrence.) and without splenectomy. Recombinant human thrombopoietin injection is only recommended to treat the patients who meet thrombocytopenia and have hemorrhage risk, and it does not apply to try to make platelets rise to normal values.

Details of clinical trial sites-

S.No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Lilavati Hospital and Research Centre, A-791, Bandra Reclamation, Bandra (W), Mumbai-400050	Institutional Ethics Committee, Lilavati Hospital and Research Centre, Dept. of research A-791, Bandra Reclamation, Bandra (W), Mumbai-400050 EC Reg. No: ECR/606/Inst/MH/2014/RR-17	Dr. Abhay Bhawe
2	Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai 400012, India.	Institutional Ethics Committee-I Seth GS Medical College and KEM Hospital, Mumbai Acharya Donde Marg Parel, Mumbai 400012, Mumbai City, Maharashtra-India. EC Reg. No: ECR/229/Inst/MH/2013/RR-19	Dr Chandrakala S
3	Mahatma Gandhi Mission's Medical College & Hospital MGM Medical College and Hospital N-6 Cidco, Aurangabad. 431003 Maharashtra, India.	MGM ethics committee for research on human subjects (MCM-ECRHS), pharmacology department, MGM medical college, n-6, cidco, Aurangabad- 431003, maharashtra, India EC Reg.No: ECR/581/Inst/MH12014/RR-17	Dr. Toshniwal Manoj Murlidhar

4	KLES Dr Prabhakar kore Hospital and MRC SMO, Second Floor, Nehru Nagar, Belagavi — Karnataka India	Institutional Ethics Committee, KLE University KLE Dr. PK Hospital and MRC Nehru Nagar Belagavi (Belgaum) Karnataka ECReg.No:ECR/211/Inst/KA/2013/RR-19	Dr Rohan Basawantrao Bhise
5	NRS Medical Colege and Hospital, 138 AJC Bose Road, Kolkata700014, West Bengal, India	ethics committee, N.R.S. medical college, 138, A.J.C. Bose Road, Kolkata700014 West Bengal, India EC Reg.No: ECR/609/Inst/WB/2014/RR-17	Dr T K Dolai
6	All India Institute of Medical Sciences, Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Ethics Committee, All India Institute of Medical Sciences, Room no. 102, 1st Floor, Old O.T. Block, Ansari Nagar, New Delhi EC Reg.No: ECR/538/Inst/DL/2014/RR-17	Dr Tulika Seth
7.	St. Johns Medical College Hospital, Sarjanpur Road Koramangala Bangalore Bengluru , (Banglore) Urban Karnataka- 560034	Institutional Ethics Committee, St. Johns Medical College Hospital Sarjapur Road Koramangala Bangalore Bengaluru (Bangalore) Urban Karnataka - 560034 India EC Reg. No. EC/RENEW/INST/2019/2825	Dr Ross Cecil
8.	Narayana Health Hospital, Health City No. 258/A, Bommasandra Industrial Area, Anekal Taluk, Bengluru (Banglore) Rural Karnataka 560099 India	Narayana Health Medical Ethics Committee, Narayana Health Hospital Health City, No. 258/A, Bommasandra Industrial Area Anekal Taluk Bengaluru Bengaluru (Bangalore) Rural Karnataka- 560099 India EC Reg. No. ECR/390/Inst/KA/2013/RR-19	Dr. Sharat Damodar

Conditions of permission for conduct of clinical trial—

The permission granted by the Central Licencing 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 Licencing 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 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;

(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;

(VII) 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;

(VIII) 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;

(IX) 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;

(X) 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;

(XI) 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;

(XII) 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;

(XIII) 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;

(XIV) 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;

(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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;

(XVI) 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;

(XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XVIII) 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.

Yours faithfully,

Place: New Delhi
Date: 04-FEB-2020

V G
SOMANI
(Dr. V. G. Somani)
Drugs Controller General (I)
Central Licencing Authority

