File No CT/47/16-DCG (I)

Clinical Trial NOC No: GCT/31/17

30294/ 10.10.16

GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

Date: 20/07/17

File No: CT/47/16-DCG (I)

To,
M/s Klinera Corporation India
401, Hill View Industrial Estate, Amrut Nagar,
L.B.S Marg, Ghatkopar (W) Mumbai-400086

Subject: Permission for conducting a Phase III clinical trial titled "A Randomized, Double-blind, Placebo- and Active-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 52 Weeks Alone and in Combination with Methotrexate (MTX) to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Are Naïve to MTX Therapy."– regarding.

Reference: Your letter No. Nil dated 03/Oct/16 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under the supervision of the investigators mentioned herein and as per **Protocol No: GS-US-417-0303, Version Amendment No 01, dated 05/July/2016** submitted to this Directorate.

1. Dr. Uma Kumar, Dept. of Rheumatology, All India Institute of Medical Sciences, Room No. 4076, 4th Floor, Teaching Block, AIIMS, Ansari Nagar, New Delhi-110029.
2. Dr. Alakendu Ghosh, IPGMER and SSKM Hospital, Dept. of Rheumatology, 244 A.J.C. Bose Road, Kolkata, West Bengal 700020.
3. Dr. T. Sudheer, Dept. of Orthopedics, Rajiv Gandhi Institute of Medical Sciences and RIMS Govt. General Hospital, Srikakulam-532001, Andhra Pradesh.
4. Dr. M. Pardha Saradhi, Dept. of Orthopedics, King George Hospital, Andhra Medical College, Visakhapatnam-530002, A P.
5. Dr. Lizarajasekhar, Nizam's Institute of Medical Sciences Panjagutta, Hyderabad-500082, Telangana.
6. Dr. Ramaswamy Subramanian, JSS Hospital, M.G. Road, Mysore 570004 Karnataka.
7. Dr. Ramakrishna Rao Uppulari, Global Hospitals, 6-1-1070/ 1 to 4, Lakdi-ka-pool, Hyderabad - 500004.
8. Dr. Vrajesh Ramakant Shah, VIROC Hospital B/5, Nivruti Cology, Aryakanya Vidhyalay Road, Karelibaug, Vadodara-390018, Gujarat.
9. Dr. Vaijayanti Lagu Joshi, Deenanath Mangeshkar Hospital and Research Centre, Near Mhatre Bridge, Erandawne, Pune, Maharashtra 411004.
10. Dr. Surendra Umesh Kamath, Dept. of Orthopedics Kasturba Medical College Hospital, Attavar, Mangalore-575001, Karnataka.
11. Dr. Somashekar S.A, Gurushree Hi-Tech Multispecialty Hospital, No. 1558, Opp. Chandra Layout Bus Stand, Chandra Layout, Vijayanagar, Bengaluru, Karnataka.

12. Dr. Lalit Duggal, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060.
13. Dr. Deepak Rai, Vinaya Hospital and Research Centre, PO No. 717, Karangalpady, Mangalore-575003, Karnataka.
14. Dr. Arvind Aggarwal, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi-110026.
15. Dr. Sundeep Kumar Upadhyaya, Indraprastha Apollo Hospitals, Dept. of Rheumatology, Sarita Vihar, Mathura Road, New Delhi-110076.
16. Dr. Avinash Agarwal, Shri Nidaan Hospitals and Hope Fertility Centre 27-Vidhut Nagar, Ajmer Road, Jaipur-302006, Rajasthan.

Kindly note that the clinical trial permission is subject to the following conditions:

a. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

b. Approval of the Ethics Committee shall be obtained before initiation of the study.

c. Clinical trials 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 study to the subject, after due analysis, shall be forwarded within 14 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 study to the subjects, 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 study 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 trial in India and other applicable regulations.

h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs 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 trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

k. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. Provided that in case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

l. 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.

Yours faithfully,

(Dr. G.N. Singh)
Drugs Controller General (I)