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GOVERNMENT OF INDIA

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Tel No: 01123236965, Fax: 01123236971
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File No: CT/41/15 - DCG (I)

Date: 18/01/16

To,

M/s Boehringer Ingelheim India Pvt. Ltd.,
1102, 11th Floor, Hallmark Business Plaza,
Guru Nanak Hospital Road, Near Guru Nanak
Hospital, Bandra (East), Mumbai-400051

Subject: Permission for conducting a Phase III clinical trial titled "A Double Blind, Randomised, Placebo-Controlled Trial Evaluating Efficacy and Safety of Oral Nintedanib Treatment For At Least 52 Weeks in Patients With 'Systemic Sclerosis Associated Interstitial Lung Disease' (SSc-ILD)."- regarding.

Reference: -Your letter no. BI/DCGI/CT/117/2015 dated 03 Sep 2015 on the subject mentioned above.

Sir/Madam,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: 1199.214 version 1.0 dated 22 July 2015, Local Amendment 1 India, dated 11 Aug 2015** submitted to this Directorate.

1. Dr. Swarnakar Rajesh Nathuram, Getwell Hospital & Research Institute, 20/1, 22/1, Khare Marg, Dhantoli, Nagpur - 440012, India.
2. Dr. Balamugesh Thangakunam, Christian Medical College, P. O. Box 3, Ida Scudder Road, Vellore - 632 004, India.
3. Dr. Mahavir Modi, Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune - 411001. Maharashtra, India.
4. Dr. Zarir Udwadia, P. D. Hinduja National Hospital & Research Center, Veer Sarvarkar Marg, Mahim (West) Mumbai - 400016, Maharashtra, India.
5. Dr. Mehta Parthiv Mahendrabhai, Sanjivani Superspeciality Hospital Pvt. Ltd. 1, Uday Park Society, Near Sunshine park, Vastrapura, Ahmedabad- 380015, Gujarat, India.
6. Dr. Mahendra Mangilal Kawedia, Jehangir Clinical Development Centre Pvt. Ltd., Jahangir Hospital Premises, 32 Sassoon Road, Pune-411001, Maharashtra, India.
7. Dr. Agarwal Vikas, SGPGI, Rae Bareilly Road, Lucknow, Uttar Pradesh- 226014, India.
8. Dr. Jugal Kishore Kadel, Care Hospital, H. No: 6-3-248/3/5/8, Road No.: 01, Banjara Hills, Hyderabad - 500004, Telangana, India.
9. Dr. Digamber Behara, Post Graduate Institute of Medical Education and Research (PGIMER), Sector-12, Chandigarh - 160 012.
10. Dr. Ujjwal Kumar Parakh, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi 110060, India.

11. Dr. Rathindranath Sarkar, Medical College and Hospital Kolkata, 88 college Street, Kolkata - 700073, West Bengal, India.
12. Dr. Vineeta Shobha, St. John's Medical College Hospital Koramangala, Sarjapur Road, Bangalore-560034, Karnataka, India.
13. Dr. Anjali Girish Rajadhyaksha, Dept. of Medicine, Seth GS Medical College & KEM Hospital, Parel, Mumbai-400012, Maharashtra, India.
14. Dr. Lokhande Rahul Maruti, B. J. Government Medical College, and Sassoon General Hospitals, Somwar Peth, Pune - 411001, Maharashtra, India.
15. Dr. Murali Mohan B. V, Mazundar Shaw Medical Centre, No.258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore 560099, Karnataka, India.
16. Dr. Uma Kumar, AIIMS, Room No: 4076, 4th Floor Teaching Block Ansari Nagar New Delhi - 110029

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

- a. **DLCO testing must be performed at accredited labs/under GLP compliant procedures and adequate documentation for compliance be maintained.**
- b. **Standard of care treatment must be provided free of cost.**
- c. 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;
- d. Approval of the Ethics Committee shall be obtained before initiation of the study;
- e. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;
- f. 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;
- g. Any report of serious adverse event occurring during clinical trial study 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;
- h. 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;
- i. 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;

- j. 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.
- k. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.
- l. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.
- m. 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.
- n. 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.
- o. 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. V.G. Somani)
Joint Drugs Controller (India) &
Licensing Authority

