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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
E-mail: dci@nic.in

File No: CT/46/14 - DCG (I)

Dated: 20/02/15

To,
M/s Boehringer Ingelheim India Pvt. Ltd.,
1102, 11th Floor, Hallmark, Business Plaza,
Gurunanak Hospital Rd, Near Gurunanak Hospital,
Bandra (East), Mumbai - 400 051.

Subject: Permission for conducting a Phase III clinical trial entitled "A randomised, double-blind, active-controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD) exacerbation in patients with severe to very severe COPD [DYNAGITO]"- regarding.

Clinical Trial NOC No.:- GCT/03/15

Reference: -Your letter no. BI/DCGI/CT/127/2014 dated 10 Oct 2014 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 supervision of the following investigators and as per the **Protocol No: 1237.19 version 1.0** dated **29 Sept 2014** submitted to this Directorate.

1. Dr. Gupta Vivek, Shree Krishna Hrudaya & critical care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur.
2. Dr. Rajesh Swarnakar, Getwell Hospital & Research Institute, 20/1, Dr. Khare Marg, Dhantoli, Nagpur.
3. Dr. Ashok Arbat, KRIMS Hospital, Dept. of Pulmonology, 275, Central Bazaar Road, Ramdaspath, Nagpur.
4. Dr. Srikanth Krishnamurthy, Sri Bala Medical Centre & Hospitals, 901, Trichy Road, Ramanathapuram, Coimbatore-641045, TamilNadu.
5. Dr. Manish Kumar Jain, SR Kalla Memorial Gastro and general Hospital Behind HSBC Bank, 78-79, Dhuleshwar Garden, C-Scheme, Jaipur, Rajasthan.
6. Dr. G Velkumar, Meenakshi Mission Hospital & Research Centre, Lake Area, Melur Road, Madurai-625107, TamilNadu.
7. Dr. Devasahayam, Dept. of Pulmonary Medicine, Christian Medical College, Vellore - 632004.
8. Dr. Amar Pazare, Seth G.S. Medical College and KEM Hospital, Dept. of Medicine, Parel, Mumbai-400012.

9. Dr. Anil Kumar Kashyap, Dayanand Medical College & Hospital, DMC & Hospital, Tagore Nagar, Civil Lines, Ludhiana, 141001, Punjab.
10. Dr. Sashibhushan, Victoria Hospital, Bangalore Medical College and Research Institute, K.R. Road, Fort, Bangalore-560002.
11. Dr. Manak C. Gujrani, Chest and TB Hospital, SP Medical College & AG of Hospitals, Bikaner-334001, Rajasthan.
12. Dr. Sanjay Tripathi, AMC Medical College & Seth L.G. general Hospital, Maninagar, Ahmedabad - 380008, Gujarat.
13. Dr. Rangaswamy, Mysore Medical College & Research Institute, Irwin road, Mysore, Karnataka-570001.
14. Dr. Mahendra Patel, Dept. of Pulmonary Medicine, Govt. Medical college and New Civil Hospital, Near Majura Gate, Ring Road, Surat-395001.
15. Dr. Nitesh Shah, Care Institute of Medical Sciences (CIMS) Hospital Pvt. Ltd. Nr. Shukan Mall, Off. Science City Road, Sola, Ahmedabad-380060, Gujarat.
16. Dr. Nageswari Arcot, SRM Medical College Hospital and Research Centre, SRM Nagar, Potheri, Kattankulathur Dist., Tamil Nadu.
17. Dr. Sundarkumar Sundarajan, GKNM Hospital, Dept. of Pulmonology, PO Box No: 6327, Pappanaickenpalayam, Coimbatore, Tamil Nadu-641037.
18. Dr. Nagaraju B, St. Theresa's Hospital, Sanathnagar, Hyderabad-500018. Telangana.
19. Dr. E Ravindra Reddy, Kamineni Hospital Pvt. Ltd., L.B. Nagar, Hyderabad, Andhra Pradesh-500068.
20. Dr. Mahesh Padukudru Anand, J S S Medical College Hospital, MG Road, Mysore-570004.
21. Dr. Parag Khatavakar, KEM Hospital, Research Centre, Chest Unit- Dept. of Medicine, 1st Floor, TDH Building, 489, Rasta Peth, Sardar Moodliar Road, Pune-411011, Maharashtra.
22. Dr. Lalita Fernandes, T.B and Chest Hospital, Goa Medical College, Goa.
23. Dr. Mohammed Samuiddin, Global Hospitals, Global Hospital, 6-1-1070/1 to 4, Lakadi-ka-pool, Hyderabad, Telangana-500004.
24. Dr. Rajiv Paliwal, Dept. of Chest Medicine, Shree Krishna Hospital & Medical Research Centre, Karamsad-388325, Gujarat.
25. Dr. Ujjawal Parakh, SIR Gangaram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060.
26. Dr. Narasinga Rao, King George Hospital (Andhra Medical Collage) Dept. of Medicine, Rajendra Prasad Ward, Vishakhapatnam-530002, Andhra Pradesh.
27. Dr. B S Nagaraj, Bowring and Lady Curzon Hospital, Bangalore Medical College and research Institute, Shivajinagar, Bangalore-560001.
28. Dr. Kartikeya Parmar, B.J. Medical College and Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat.
29. Dr. Ram S Kaulgud, Karnataka Institute of Medical Sciences, Vidyanagar, Hubli-580022.
30. Dr. Uma Maheshwari, M. S. Ramaiah Clinical Research Centre, M.S. Ramaiah Advanced Learning Centre, First Floor, Gnanagangothri Campus, Gate-4, New BEL Road, MSRIT Post, Bangalore -560054.
31. Dr. Subhasish Ghosh, Apollo Gleneagles Hospitals, Dept. of Pulmonology, day care, 03rd Floor, 58, Canal Circular Road, Kolkata-700054. West Bengal.
32. Dr. Mahavir Modi, Grant Medical Foundation, Ruby Hall Clinic, 40 Sassoon Road, Pune-411001, Maharashtra.

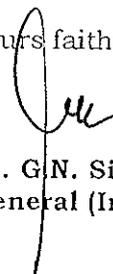
33. Dr. Jyotsana Joshi, T N Medical College & B Y L Nair Hospital, Dept. of Pulmonary Medicine, OPD Building 2nd Floor, A L Nair Road, Mumbai Central-400008.
34. Dr. Ajeet Singh, SMS Hospital, Division of Allergy & Pulmonary Medicine, F-1, Dhanvantri OPD Block, SMS Hospital, Jaipur-302004, Rajasthan.
35. Dr. JanakKhambholja, Smt N H L Municipal Medical College, Ellis Bridge, Ahmedabad-380006, Gujarat.
36. Dr. Parthiv Mehta, Sanjivani Super speciality Hospital Pvt. Ltd., Uday Park Society, Near Sunrise Park, Vastrapur, Ahmedabad-380015.
37. Dr. Paramjyothi, Nizams Institute of Medical Sciences (NIMS), Punjagutta, Hyderabad-500082.
38. Dr. Narendra Khippal, Institute of Respiratory Disease, S.M.S. Medical College & hospital, Subhash Nagar Shopping Centre, Shastri Nagar, Jaipur-302016, 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 ten 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 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.
- k. 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.
- l. In addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials. All the Sponsors /Investigators /Institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are required to adhere to this requirement of audio-visual recording of informed consent process of trial subjects.
- m. 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 (India)