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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)
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File No: CT/59/15 – DCG (I)

Date: 21/06/16

To,
M/s Novartis Healthcare Pvt. Ltd.,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai-400018

Subject: Permission for conducting a Phase III clinical trial titled “A multicenter, randomized, 52-week, double-blind, parallel group, active controlled study to compare the efficacy and safety of QVM149 with QMF149 in patients with asthma.” – regarding.

Reference: - Your letter No. Nil dated 16 Dec 2015 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 and under the supervision of the following investigators as per the Protocol No: CQVM149B2302, v03 Clean Version (Amended Protocol Version), dated 08 Oct 2015 submitted to this Directorate.

1. Dr. Bhagirath B. Solanki, B. J. Medical College & Civil Hospital, Asarwa, Ahmedabad- 380 016, Gujarat, India.
2. Dr. Suraj. K. P, Institute of Chest Diseases, Department of Pulmonary Medicine, Govt. Medical College, Kozhikode-673008, Kerala, India.
3. Dr. Vasireddy Aruna, Dept. of Pulmonary, Old Govt. Hospital, Tow Town, Hanumanpet, Vijayawada-520002, Andhra Pradesh.
4. Dr. K.N.Mohan Rao, Department of TB and Chest Disease, Rajarajeshwari Medical College and Hospital, Kambipura, Mysore Road, Bangalore- 560074.
5. Dr. Animesh Arya, Dept. of Respiratory Medicine Sri Balaji Action Medical Institute, A-4, Paschim Vihar, New Delhi-63, India.
6. Dr. K.K.Sharma, Eternal Heart Care Centre & Research Institute, 3A, Jagatpura Road, Near Jawahar Circle, Jaipur 302020, Rajasthan, 302020.
7. Dr. Sanjay Khator, Malpani Multispecialty Hospital SP-6, Road No-01, V.K.I, Sikar Road, Jaipur, Rajasthan- 302013.
8. Dr. Ashish Kumar, Indian Asthma Care Society, R-3-Sector-6 Vidhyadhar Nagar, Near Jaipur Rajasthan, 302023.
9. Dr. Ujjwal Parakh, Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi- 110060.
10. Dr Vivek Gupta, Meditrina Institute of Medical Sciences, 278, Central Bazar Road, Ramdaspath, Nagpur 440010.
11. Dr Anil Kishanrao Sontakke, Dept. of Pulmonary, NKP Salve Institute of Sciences & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road, Nagpur 440019.

12. Dr. Janak A Bhavsar, SAL Hospital, Opposite Doordarshan Tower, Drive-in-road, Thaltej, Ahemedabad-380054.
13. Dr. Ashish Goyal, Medipoint Hospitals Pvt. Ltd. 241/1, New D.P.Road, Aundh, Pune 411007, Maharashtra, India.
14. Dr. Lakshmi Kumari, Lalitha Super Specialities Hospital, Kothapet, Guntur-522001, Andhra Pradesh, India.
15. Dr. Sushant Meshram, Dept. of Pulmonary Medicine, B.J. Govt. Medical College & Sassoon General Hospital, near Pune Railway station, Pune-411001.
16. Dr. Anand Kumar, Dept. of Pulmonology, GSVM Medical College, Near Rawatpur Crossing, Kanpur-208005.
17. Dr. Zuber Ahmad, Dept. of TB & Respiratory Diseases, JN Medical College, JN Medical College & Hospital, AMU, Aligarh-202002, Uttar Pradesh.
18. Dr. Hemalatha VS, Sree Narayana Institute Medical Sciences, Chalakka, N. Kuthiyathod. P.O, Ernakulam, Kerala-683594
19. Dr. Vikas Acharya, Dept. of pulmonary medicine Kasturba Medical College Hospital Attavar, Mangalore 575001, Karnataka.
20. Dr. Balamugesh, Dept. of Pulmonary medicine, Reasearch Laboratory, P. O. Box-3, Christian Medical, College, Ida scudder Road, Vellore-632004.
21. Dr. Banani Jena, Dept. of Pulmology, IMS & SUM Hospital, K-8, Kalinga Nagar, Bhubaneswar-751003, Orissa.
22. Dr. Vijil Rahulan, Global Health City, 439, Cheran Nagar, Perumbakkam, Chennai-600100.
23. Dr. Ajay Godse, Bhakti Vedanta Hospital & Research Insitute, Shrishti Complex, Bhakti Vedanta Swami Marg, Mira Road (East), Thane Maharashtra-401107.
24. Dr. Raja Dhar, Fortis Hospital, 730 Anandapur, Kolkata-700107, West Bengal.
25. Dr. Amit Kumar Mandal, Fortis Hospital, Sector 62, Phase-VIII, Mahali Pb 160062.
26. Dr. Velkumar Gopal, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai-625107.
27. Dr. Rajeev Adkar, Noble Hospital Pvt. Ltd. 153, Magarpatta City Road, Maharashtra-411013.
28. Dr. Sailal M, KVM Hospital, P.B. No. 30 Cherthala, Kerala-688524.
29. Dr. Supraja Kalyana Raman, Madras Medical Mission, 4-A, Dr. J. Jayalalitha Nagar, Mogappair, Chennai, Tamilnadu- 600037.
30. Dr. Neeraj Gupta, Paras Hospital C-1, Shusant lok-1, Sec-43, Gurgaon, Haryana-122002.
31. Dr. Ashfaq Hasan, Owaisi Hospital and Research Centre, Deccan Collgege of Medical Sciences, Kanchanbagh, Hyderabad-500058.
32. Dr. Nagaraju B, St. Theresa's Hospital, Erragadda, Sanath Nagar, Hyderabad-500018, Telangana State.
33. Dr. Tapaswi Krishna, Global Clinical Research Services Global Hospitals, 6-1-1070/1 to 4, Lakdi-ka-pool, Hyderabad 500004, Telangana.
34. Dr. Ram S Kaulgud, Karnataka Institute of Medical Sciences (KIMS), Vidyanagar, Hubli-580022, Karnataka, India.
35. Dr. Kesavan Nair Veerendran Nair, Kerala Institute of Medical Sciences, Anayara P O, P. B. No.1, Trivandrum-695029.
36. Dr. Vishwanath Bellad, BGS Global Hospitals, BGS Health & Education City, #67, Uttarahalli Road, Kengeri, Bangalore - 560060, Karnataka, India.
37. Dr. Jagdish Kumar Rawat, Shri Guru Ram Rai Institute of Medial Secience & Shri Mahant IndiresH Hospitals, Patel Nagar-Dehradun Uttarakhand.
38. Dr. Patel Tushar Bhagvatprasad, Sterling Hospital, Sterling Hospital Road, Memnagar Ahmedabad-380052.
39. Dr. Manish Shankar, Dept. of TB & Chest Indira Gandhi Insitute of Medical Sciences, Sheikhpura, Patna-800014.

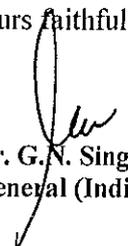
40. Dr. Surendra Kumar, S. P. Medical College and A.G. of Hospital, Near Medicine ICU, Ground Floor, Bikaner, Rajasthan-334001.
41. Dr. Rangaswamy, KR Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka.
42. Dr. Raja Bhattacharya, Medical College & Hospital, 88, College Street, Kolkata-700073.
43. Dr. Guruprasad Srinivasa, Manipal Hospital, 98, HAL Airport Road, Bangalore-560017, Karnataka.

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 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 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. 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.
 - 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)