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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-110 002
Tel No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/57/14 – DCG (I) Dated: 24/04/15

To,

M/s Pfizer Ltd, Pfizer Centre,
Patel Estate, Off S. V. Road,
Jogeshwari (W), Mumbai – 400 102.

Subject: Permission for conducting a clinical trial entitled "Phase 3 multi-center, double-blind, randomized, placebo-controlled, parallel group evaluation of the efficacy, safety and tolerability of Bococizumab (PF-04950615), in reducing the occurrence of major cardiovascular events in high risk subjects"– regarding.

Clinical Trial NOC No.:- GCT/14/15

Reference: - Your letter No. CT/B1481022/2014/001 dated 10 Dec 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: B1481022 protocol amendment 1 dated 01 Oct 2014** submitted to this Directorate.

1. Dr. Jugal Bihari Gupta, S.R. Kalla Memorial Gastro & General Hospital, 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur - 302001, Rajasthan.
2. Dr. Raghavendra N. Belgaonkar, Sushruta Multispeciality Hospital & Research Center Private Limited, P.B. Road, Vidyanagar, Hubli - 580021, Karnataka.
3. Dr. Chopada Manojkumar Bhavarilal, Chopda Medicare & Research Center Pvt. Ltd, Magnum Heart Institute, 3/5, Patil Lane No.1, Laxmi Nagar, Near K B H Vidyalaya, Canada Corner, Nashik - 422005, Maharashtra.
4. Dr. Gadkari Milind Avdhoot, Department of Cardiology, 5th Floor, Diamond Jubilee Building, KEM Hospital Research Centre, 489, Rasta Peth, Sardar Moodliar Road, Pune -411011, Maharashtra.
5. Dr. Mahesh Fulwani, Shri Krishna Hrudayalaya and Critical Care Centre, Congress Nagar Square, Opp. New English School, Tikekar Road, Dhantoli, Nagpur-440012, Maharashtra.
6. Dr. Milan Chag, Care Institute of Medical Sciences, Near. Shukan Mall, Off. Science City Road, Sola, Ahmedabad -380060, Gujarat.
7. Dr. Shantanu Sengupta, Sengupta Hospital and Research Institute, Ravinagar Square, Nagpur- 440033, Maharashtra.
8. Dr. Naveen Jamwal, M V Hospital and Research Center, 314/30, Mirza Mandi Chowk, Lucknow- 226003, Uttar Pradesh.

9. Dr. Tejas Patel, Apex Heart Institute, Block No. G-K, Mondeal Business Park, Near Gurudwara, S. G. Highway, Ahmedabad-380054, Gujarat.
10. Dr. Priya Palimkar, Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Hospital Premises, 32, Sassoon Road, Pune - 411001, Maharashtra.
11. Dr. Pankaj Akholkar, GMERS Medical College & Civil Hospital, Sola, Ahmedabad - 380060, Gujarat.
12. Dr. Pabhu S, Victoria Hospital, Bangalore Medical College & Research Institute, Room No. 72/A, 2nd Floor, C Block, Fort, K.R. Road, Bengaluru-560002, Karnataka.
13. Dr. Jyotsna. M. Professor, Dept of Cardiology, Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad, Telangana -500 082.
14. Dr. Adikesava Naidu, Osmania General Hospital, Department of Cardiology, QQDC building, 2nd floor, Afzalgunj, Hyderabad, Telangana-500012.
15. Dr. Neelkanth Karandikar, B. J. Govt. Medical College & Sasoon General Hospital, Near Pune Railway Station, Pune - 411 001, Maharashtra.
16. Dr. Dipti Anil Chand, Government Medical College & Hospital, Dept. of Medicine, Hanuman Nagar, Nagpur- 440003, Maharashtra.
17. Dr. Vageesh Ayyar, Department of Endocrinology, St. John's Medical College and Hospital, Sarjapur Road, Koramangala Bangalore 560 034, Karnataka.
18. Dr. A. E. Padmakumar, Mediciti Hospitals, 5-9-22, Opp. Secretariat, Hyderabad - 500 063, Andhra Pradesh.
19. Dr. Keshavamurthy Chakrabhavi Basavegowda, Vikram Hospital Private Limited, No.46, Vivekananda Road, Yadavagiri, Mysore 570 020, Karnataka.
20. Dr. Hiremath Murughesh Shantaveeraya, Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune -411 001, Maharashtra.
21. Dr. Manish Kumar Sharma, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi - 110060.
22. Dr. Gurpreet Singh, Dayanand Medical College and Hospital, Unit Hero DMC Heart Institute, Tagore Nagar, Ludhiana - 141001, Punjab.
23. Dr. Ajay S Chaurasia, Topiwala National Medical College and B.Y.L Nair Charitable Hospital, AL Nair Road, Mumbai, Maharashtra- 400 008.
24. Dr. Vijay Pathak, SMS Medical College Hospital, Jawaharlal Nehru Marg, Jaipur - 302 004, Jaipur, Rajasthan.
25. Dr. Ravindra Kulkarni, Ashwin medical Foundation's Moraya Mulitspeciality Hospital, Opp Main Chinchwad, Power House Chowk, Chinchwadgaon, Pune - 411033, Maharashtra.
26. Dr. Srikanth. K. V., Narayana Institute of Cardiac Science, 258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore-560 099, Karnataka.
27. Dr. Vinod Sharma, National Heart Institute, 49-50, Community Centre, East of Kailash, New Delhi-110 065.
28. Dr. Prakash Chandwani, Heart and General Hospital, 7, Vivekanand Marg, C-Scheme, Jaipur-302 001, Rajasthan.
29. Dr. Anupama V Hegde, M. S. Ramaiah Clinical Research Centre, 1st Floor, M.S.Ramaiah Advanced Learning Centre, Gate No.3, Gnanagangotri Campus, M.S. Ramaiah Medical College &Hospitals, New BEL Road, MSRIT Post, Bangalore - 560054, Karnataka.
30. Dr. Abraham Oomman, Apollo Hospital, 645 & 646, Thiruvotriyur High Road, Tondiarpet, Chennai-600 081, Tamil Nadu.
31. Dr. Shamanna Seshadri, Manipal Hospitals, # 98, HAL Airport Road, Bangalore-560 017, Karnataka.
32. Dr. Rajesh K. Vijayvergiya, Advanced Cardiac Care, Post Graduate Institute of Medical Education and Research (PGIMER), Sector 12, Near Punjab University, Chandigarh-160012, Punjab.

33. Dr. Dilipkumar Bhagwandas Gheewala, GMERS Medical College and Hospital, Halar Road, Nanakwada, Valsad-396001, Gujarat.
34. Dr. Biswakes Majumdar, Institute of Post Graduate Medical Education and Research (IPGME&R), 244, Acharyya Jagadish Chandra Bose Road, Calcutta-700020, West Bengal.
35. Dr. Kaushik Mukherjee, Medical College and Hospitals, Kolkata, Department of Thoracic & Cardiovascular Surgery, 88, College Street, Kolkata – 700 073, West Bengal.
36. Dr. Mahesh Govindbhai Solu, Government Medical College, New Civil Hospital, Outside Majuragate, Ring Road, Surat-395001, Gujarat.
37. Dr. Anil Ranjeetmal Jain, SAL Hospital, Opp. Doordarshan, Drive-in Road, Ahmedabad-380 054, Gujarat.
38. Dr. Bhupesh Rajnikant Shah, Jivraj Mehta Hospital, Ratubhai Adani, Arogyadham, Dr. Jivraj Mehta Marg, Ahmedabad- 380 007, Gujarat.
39. Dr. Sachin Narendra Patil, Aster Aadhar Hospital, R. S. No.628, 'B' Ward, Near Shastri Nagar, KMT Workshop, Kolhapur-416 012, Maharashtra.
40. Dr. Pragnesh Rameshchandra Shah, Apple Hospital, Udhan Darwaja, Ring Road, Surat- 395 002, Gujarat.
41. Dr. Devangkumar Maheshchandra Desai, Unicare Heart Institute, Unicare Hospital of SGCCPL, Acme Plaza, B- Wing, Near Sosyo Circle, Canal Road, Surat-395 002, Gujarat.
42. Dr. Manish Ravindra Singhavi, Nirmal Hospital Pvt. Ltd, Ring Road, Surat-395 002, Gujarat.
43. Dr. Nirav Chandulal Bhalani, Rhythm Heart Institute, Lakulesh Park Society, Near Sadhuvasvani School, Airport Circle, New VIP Road, Vadodara – 390 022, Gujarat.
44. Dr. Parshottam Govindbhai Koradia, BAPS - Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat – 395 009, Gujarat.
45. Dr. Rajat Ramji Gandhi, Vintage Hospital & Medical Research Centre Pvt. Ltd, Caculo Enclave, St. Inez, Panaji, Goa-403 001.
46. Dr. Santanu Datta, Nightingale Hospital, Nightingale Diagnostic and Medicare Centre Pvt. Ltd, 11, Shakespeare Sarani, Kolkata-700 071, West Bengal.
47. Dr. Balaji Ramagiri, Krishna Institute of Medical Sciences Ltd. (KIMS), Minister Road, Secunderabad-500 003, Andhra Pradesh.
48. Dr. Nirmal Kumar, Care Hospital, #5-4-199, Jawaharlal Nehru Road, Hyderabad- 500 001, Telangana.
49. Dr. P. Nagasri Haritha, Government General Hospital, Guntur – 522 004, Andhra Pradesh.
50. Dr. Keyur Madan Brahme, Medical College Baroda and Sir Sayajirao General (SSG) Hospital, Jail Road, Indira Avenue, Vadodara – 390001.
51. Dr. Aparna Prasanna Patange, Krishna Institute of Medical Sciences and Deemed University Karad, Pune-Bangalore Highway 4, Malkapur, Karad, Dist. Satara – 415 110, Maharashtra.
52. Dr. Jeet Ram Kashyap, Govt. Medical College & Hospital, Sector-32, Chandigarh-160 030, Punjab.
53. Dr. Rishi Sethi, Dept. of cardiology, King George's medical University, U.P, Lucknow- 226 003.

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. V.G. Somani)
Joint Drugs Controller (India)