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
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File No: CT/17/000006

To,

M/s Quintiles Research (India) Private Limited,
B-101-106, Shapath IV, Opp. Karnavati Club,
Sarkhej-Gandhinagar Road, Ahmedabad - 380051.

Subject: Permission for conducting a clinical trial titled "Pemafibrate to Reduce Cardiovascular Outcomes by Reducing Triglycerides in Patients with Diabetes (PROMINENT)."– regarding.

Reference: Your online submission No. GCT/Form44/FF/2017/1803 (GCT/06/17) dated 03/02/2017 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 investigators mentioned below and as per the **Protocol No. K-877-302, Version 1.0, dated 16/Nov/16** submitted to this Directorate.

1. Dr. Atul Damodar Abhyankar, Shree Mahavir Health and Medical Relief Society, Shri Bachubhai Dahyabhai Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Athwagate, Ring Road, Surat – 395001, Gujarat, India.
2. Dr. Shah Bhupesh Rajnikant, Dr. Jivraj Mehta Smarak Health Foundation, Bakeri Medical Research Center, Ratubhai Adani Arogyadham, Dr. Jivraj Mehta Marg, Ahmedabad-380007, Gujarat.
3. Dr. Jeet Ram Kashyap, Government Medical College & Hospital, Sector 32, Chandigarh 160030, India.
4. Dr. Mahpaekar Mashhadi, Dharmsinh Desai Memorial Methodist Institute of Cardiology and Cardiovascular surgery (DDMM Heart Institute) Mission Road, Nadiad 387002, Gujarat, India.
5. Dr. Bhagwat Ajit Raghunath, Kamalnayan Bajaj Hospital, Marathawada Medical & Research Institute, Gut No.43, Satara Parisar, Bajaj Marg, Beed Bypass Road, Aurangabad-431005, Maharashtra, India.
6. Dr Ram Anil Raj Manni Rajagopal, Rajarajeswari Medical College & Hospital, Rajrajeshwari Heart Centre Bangalore, Department Cardiology, #202, Kambipura, Mysore Road, Bangalore-560074, Karnataka, India.
7. Dr Harkut Pankaj Vijaykumar, Meditrina Institute of Medical Sciences, 278, Central Bazar road, Ramdaspeth, Nagpur-440010, Maharashtra, India.
8. Dr. Dhurjati Prasad Sinha, Institute of Post Graduate Medical Education & Research, 244, Acharya Jagdish Chandra Bose Road, Kolkata-700020, West Bengal.
9. Dr. Kajal Ganguly, Nilratan Sircar Medical College & Hospital, 138, AJC Bose Road, Kolkata-700014, West Bengal.

10. Dr. Sunita Aggarwal. Department of Medicine, Maulana Azad Medical college and associated Lok Nayak, Govind Ballabh Pant Hospital, Guru Nanak Eye Center, New Delhi-110002, Delhi.
11. Dr. Nirav Chandulal Bhalani, Rhythm Heart Institute-Unit of Synergy lifecare Pvt. Ltd., Near Siddharth Bunglows, Sama-Savli Road, Vadodara-390022, Gujarat.
12. Dr. Washimkar Sunil Nilkanthrao, Department of Cardiology, Super Speciality Hospital, Government Medical College & Hospital, Tukdoji Square, Nagpur-440009, Maharashtra.
13. Dr. Karandikar Neelkanth Gopalrao, Sassoon General Hospital, Jayprakash Narayan Road, Near Pune Railway Station, Pune- 411001, Maharashtra.
14. Dr. Dhiman Kahali, BM Birla Heart Research Centre, 1/1, National Library Avenue, Kolkata-700027, West Bengal.
15. Dr Jugal Bihari Gupta, Eternal Hospital, Unit of Eternal Heart Care Centre & Research Institute Pvt. Ltd., 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan.
16. Dr. Abid Hussain, Fortis Flt. Lt. Rajan Dhall Hospital, Sector-B, Pocket 1, Aruna Asaf Ali Marg, Vasant Kunj, New Delhi-110070.
17. Dr. Kothiwale Veerappa Annasaheb, KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi- 590010, Karnataka.
18. Dr. Debabrata Roy, NH-Rabindranath Tagore International Institute of Cardiac Sciences, Premises No: 1489, 124, Mukundapur, E. M. Bypass, Kolkata – 700099, West Bengal.
19. Dr. Shamanna Seshadri Iyengar, Manipal Hospital, #98, HAL Airport Road, Bengaluru- 560017, Karnataka.
20. Dr. Ravi Kumar Gurugubelli, King George Hospital, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh.
21. Dr. Sanjay Mittal, Medanta – The Medicity, Sector-38, Gurgaon, Haryana-122001.
22. Dr. Vishal Rastogi, Fortis Escorts Heart Institute, Okhla Road, New Delhi-110025.
23. Dr. Anup Kumar Boro, Guwahati Neurological Research Center (GNRC) Ltd., GNRC Complex, Dispur, Guwahati-781006, Assam.
24. Dr. Keshava Ramaiah, Fortis Hospital, No 14, Cunningham Road, Bangalore – 560052, Karnataka.
25. Dr. Amit Kumar Chaurasia, BLK Super Speciality Hospital, Pusa road, New Delhi- 110005.
26. Dr. Mullasari Ajit Sankardas, The Madras Medical Mission, 4-A, Dr. J. Jayalalitha Nagar, Mogappair, Chennai, Tamil Nadu-600037.

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 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,

GYANENDRA NATH SINGH

Digitally signed by GYANENDRA NATH SINGH
Date: 2017.07.18 10:10:08 +05'30'

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