

GOVERNMENT OF INDIA

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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
E-mail: dci@nic.in

File No: CT/42/16-DCG (I)

Date: 20-06-17

To,

M/s PPD Pharmaceutical Development India Pvt. Ltd.,
101-A wing, Fulcrum, Hiranandani Business Park,
Sahara Road, Andheri East, Mumbai-400059

Subject: Permission for conducting a Phase IIIa clinical trial titled "A Phase 3 Randomized, Open-label (Sponsor-blind), Active-controlled, Parallel-group, Multi-center, Event Driven Study in Dialysis Subjects With Anemia Associated With Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Recombinant Human Erythropoietin, Following a Switch from Erythropoietin-stimulating Agents."— regarding.

Reference: Your letter No. PPD/REG/596641804/2016/001 dated 13/Sep/16 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 the supervision of the investigators mentioned herein and as per Protocol No: 200897, Amendment No. 92, dated 12/Oct/16 submitted to this Directorate.

1. Dr. Manju Aggarwal, Artemis Hospitals, Sector 51, Gurgaon, Haryana-122001.
2. Dr. Alok Jain, Fortis Escorts Hospital, Jawaharlal Nehru Marg, Near Malviya Nagar, Jaipur, Rajasthan- 302017.
3. Dr. Sanjeev Jasuja, Indraprastha Apollo Hospitals, Delhi Mathura Road, Sarita Vihar, New Delhi 110075.
4. Dr. Ravindra Prabhu A. Kasturba Medical College and Hospital, Manipal University, Manipal – 576104.
5. Dr. Manju L. Noorul Islam Institute of Medical Science (NIMS) & Research Foundation, NIMS MEDICAL, Aralamoodu, Neyyattinkara Thiruvananthapuram-695 123.
6. Dr. Anil Bhatta, Sir Ganga Ram Hospital Sir Ganga Ram Hospital Marg, Rajinder Nagar New Delhi-110060.
7. Dr. Prakash Datt Israni, Sterling Hospital, 2nd Floor, Sterling Hospital, Sterling Hospital Road, Wemnagar, Ahmedabad-380052.
8. Dr. V. Srinivas, N. S. Chaitanya Prasad, Prudhvi Hospital, Dr. Virendra Desai Road, Nadiad-387001, Kheda District, India.
9. Dr. J. S. Jelekar, Aditya Birla Memorial Hospital, ABMH Marg, Thergaon Chinchwad, Pune – 411005.

10. Dr. Alan F. Almeida, P.D. Hinduja National Hospital & MRC Veer Savarkar Marg, Mahim, Mumbai-400016.
11. Dr. May Kher, Fortis Escorts Hospitals, Okhla Road, New Delhi-110025.
12. Dr. Georgi Abraham, The Madras Medical Mission, 4-A, Dr. J.J Nagar, Mogappair, Chennai – 600037.
13. Dr. Sundar Sankaran, Columbia Asia Referral Hospital, No 26/4, Brigade Gateway, Beside Metro-cash & carry west, Malleshwaram, Bengaluru – 560055..
14. Dr. Mahesh Pokade, Inamdar Multispeciality Hospital, Hospital Building, S.No. 15, Fatima Nagar, Pune-411040.
15. Dr. Mahesh Eswarappa, M S Ramaiah Clinical research Center, First floor, M. S. Ramaiah Advanced Learning center, Granagangothri campus, Gate-4, New BEL Road, MSRIT post, Bangalore-560054.
16. Dr. Jacob George, Government Medical College, Ulloor Road, Thiruvananthapuram, Kerala – 69.01, India.
17. Dr. Jaynikumar Khandekar, Ganga CARE Hospital, 3 Farmland Panchsheel square, Nagpur-440011.
18. Dr. Suleetha Menemadathil, Government Medical College, Kozhikode, Kerala – 673008.
19. Dr. SubbaRao Budithi, Apollo Hospitals, 21 Greams Lane, Off Greams Road, Chennai – 600005.
20. Dr. Pijsekhar Chakravarthy, Star Hospitals, Road No 10, Banjarahills, Hyderabad, Telangana, India – 500034.
21. Dr. Aman Chhabra, Max Super-Specialty Hospital, 1 Press Enclave Road Saket, New Delhi 110017.

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 1 of Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.
- b. Approval of the Ethical Committee shall be obtained before initiation of the study.
- c. Clinical trial 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 14 days of its occurrence as per Appendix XI and in compliance with the requirements specified in Schedule 1.
- f. In case of any 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 127(1) AB 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 study sites, to inspect, search and seize any record, data, document, books, investigational drugs, and 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 trials 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 conduct of 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 on a 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 on a record.
 - l. It may be noted that the grant of permission to conduct clinical trials with the drug does not constitute any approval of the clinical trial data generated with the drug, permission to market this drug shall be granted only when it is formally granted to you.

Yours faithfully,



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

