

7001/04.03.15

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/07/15 - DCG (I)

Date: 17/08/15

To,
 M/s Johnson and Johnson Pvt. Ltd.,
 Arena Space, Off J.V.L.R,
 Behind Majas Depot,
 Jogeshwari (E), Mumbai-400 060.

Subject: Permission for conducting a Phase III clinical trial entitled "A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects with Type 2 Diabetes Mellitus and Diabetic Nephropathy"- regarding.

Reference: -Your letter No. GCO-2015/003dated 26Feb 2015on 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: 28431754DNE3001 Amendment INT-2dated 03Feb 2015** submitted to this Directorate.

1. Dr. Dr. Narayan Prasad, Department of Nephrology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh, 226 014.
2. Dr. Satish Balan, Kerala Institute of Medical Sciences (KIMS), Post Box-1, Annayara P.O, Trivandrum, Kerala.
3. Dr. Dinesh Khullar, Max Healthcare Super Speciality Hospital, Department of Nephrology and Kidney Transplant Medicine, 2- press enclave road, Saket, New Delhi.
4. Dr. Dhananjai Agarwal, Dept. of Nephrology, S. M. S. Medical College & Hospital, Jawaharlal Nehru Marg, Jaipur, Rajasthan, 302 004.
5. Dr. P. Jayameena, PVS Hospital (P) Ltd., Railway Station Road, Calicut, Kerala, 673 002.
6. Dr. Manju Thampi, Noorul Islam Institute of Medical Sciences(NIMS) & Research Foundation, NIMS Medicity , Aralummodu, Neyyanttinkara, Trivandrum, Kerala-695 123.
7. Dr. Alan F Almeida, Dept. of Nephrology, P. D. Hinduja National Hospital and Research Center, Veer Savarkar Marg, Mahim, Mumbai, 400 016.
8. Dr. D Sree Bhushan Raju, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana, 500082.
9. Dr. Deepak Dewan, Ajanta Hospital & Research Centre, 765-ABC Complex, Near Krishna Cinema, Kanpur Road, Alambagh, Lucknow, Uttar Pradesh, 226 005.

10. Dr. Hansraj Alva, Vinaya Hospital and Research Center, 717, Karangalapady, Near Medicare Centre, Mangalore-575 003.
11. Dr. Manisha Sahay, Osmania General Hospital, Department of Nephrology, QQDC Building, Afzalgunz, Hyderabad.
12. Dr. Dhananjay Kumar Sinha, Heritage Hospital Ltd, Lanka, Varanasi, Uttar Pradesh, 221 005.
13. Dr. Sreedhar Reddy, Department of Nephrology, Krishna Institute of Medical Sciences, Minister Road, Hyderabad, Telangana, 500 003.
14. Dr. V. Ramesh Chandra, Department of Nephrology, King George Hospital, Maharanipecta, Vishakapatnam, Andhra Pradesh, 530 002.
15. Dr. Abraham Oomman, Department of Internal Medicine, Ramana Maharshi Rangammal Hospital, Athivandal Tiruvannmalai, Tamilnadu.
16. Dr. Gopalakrishnan Natarajan, Madras Medical College and Government General Hospital, Dept. of Nephrology, Chennai, Tamilnadu - 600 003.
17. Dr. Dinesh Jain, Dayanand Medical College & Hospital, Civil Lines, Ludhiana, Punjab, 141 001.
18. Dr. Edwin Fernando, Department of Nephrology, 3rd Floor, New Tower Building, Stanley Medical College, 305 OSH Rd, Royapuram, Chennai, Tamil Nadu, 600 001.
19. Dr. Sreelatha M, Government Medical College, Medical College P O, Calicut, Kerala-673 008.

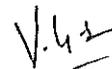
Kindly note that the clinical trial permission is subject to the following conditions:

- 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) and
Licensing Authority

