16020/29.11.19
2805/28.02.20

File No. 4-12/2016-DC (Pt. File)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 09 MAR 2020

To,

M/s. Johnson & Johnson Pvt. Ltd.,
L.B.S. Marg, Mulund (W), Mumbai-400080.

Subject: **Permission for conducting Phase IV Clinical Trial with FDC of Canagliflozin + Metformin HCl (50mg + 500mg, 150mg + 500mg, 50mg+850mg, 150mg + 850mg, 50mg + 1000mg & 150mg + 1000mg) film coated tablets (Vide Protocol No. 28431754DIA4032, dated 31.10.2018)- regarding.**

CT No. **CT-06-26/2020**

Sir,

Please refer to your letter no. REG/JB/PMS/2020/025 dated 28.02.2020 on the subject mentioned above. This Directorate has no objection to your conducting clinical trial with the said drug under the supervision of following investigators mentioned and as per the **Vide Protocol No. 28431754DIA4032, dated 31.10.2018** submitted to this Directorate.

1. Dr Mohan Magdum, Jehangir Clinical Development Centre, Pvt. Ltd., Jehangir Hospital Premises 32, Sassoon Road, Pune- 411001.
2. Dr Faraz Farishta, Thumbay Hospitals, 16-6-104 to 109, Old Kamal Theatre, Chaderghat, Hyderabad- 500024.
3. Dr. Sreenivasa Murthy, Lifecare Hospital & Research Centre, #2748/2152, M.L.N. Enclave, 16th E Cross, 8th main, D Block, Next to Corporation Bank, Sahakar Nagar, Bangalore- 560092.
4. Dr Balamurugan Ramanathan, Kovai Diabetes, Speciality Centre & Hospital, No. 15, Vivekananda Road, Ramnagar, Coimbatore-641009.
5. Dr. A. G. Unnikrishnan, Chellaram Diabetes Institute, 1st floor, Lalani Quantum, NH-4, Opp. Calsoft Building, Bavdhan (Budruk), Pune- 411021, Maharashtra, India.
6. Dr Jothydev Kesavadev, Jothydev's Diabetes Research Centre, JDC Junction, Konkalam Road, Mudavanmugal, Trivandrum- 695032, Kerala, India.

The clinical trial permission is subject to the following conditions:-

a. Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
b. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:
   i. Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:
   ii. Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site:

c. In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
d. The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
e. Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
f. Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
g. Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
h. Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority.
i. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
j. Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
k. In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
l. In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
m. The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
n. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;
o. The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
p. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

q. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

r. In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial 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, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015;

s. **Additional Clinical Trial sites, distributed geographically should be included for conducting the trial and details of the same shall be submitted before initiation of the study.**

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-
All Zonal/Sub Zonal offices of CDSCO.