35959/13.12.18

File No. 4-42/2016-DC (Pt. Mylan)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No. : 011-23236965
Fax No. : 011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 23 APR 2019

To,

M/s. Mylan Laboratories Ltd.,
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik-422113, Maharashtra.

Subject: **Permission for conducting phase IV clinical trial with FDC of Daclatasvir Dihydrochloride Eq. to Daclatasvir 60mg + Sofosbuvir 400mg film coated tablets (Vide Protocol No. MYL-MHD-4001, Version No. 2.0, dated 15.11.2018) -regarding.**

CT No. **CT/Drugs/40/2019**

Sir,

Please refer to your letter no. RA/MLL/DCGI/18/044 dated 11.12.2018 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 Daclatasvir Dihydrochloride Eq. to Daclatasvir 60mg + Sofosbuvir 400mg film coated tablets (Vide Protocol No. MYL-MHD-4001, Version No. 2.0, dated 15.11.2018 submitted to this Directorate.

1. Dr. Ajit Sood, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana, Pujab-141001.
2. Dr. Dawney Zachariah, Lourdes Hospital, Ernakulam, Kochi-682012, Kerala.
3. D. Premashis Kar, Max Super Speciality Hospital, Vaishali (A unit of Crosslay Remedies Ltd.) W-3, Sector-1, Vaishali, Ghaziabad-201012, Uttar Pradesh.

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 duly registered with the office of DCG (I) shall be obtained before initiating the clinical trial.
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. 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.

j. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

k. 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.

l. **Word 'decompensation' shall be removed from the exclusion criteria.**

m. **The minimum number of patients shall be 250 in the study.**

n. **The clinical sites shall be geographically distributed across the country.**

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

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