3145/29.01.18

File No. 4-101/2017-DC (Pt. 1)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

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

Dated: 14 MAR 2018

To,

M/s. Ajanta Pharma Ltd.,
Ajanta House Charkop, Kandivli West, Mumbai-400067.

Subject: Permission for conducting phase III clinical trial with FDC of Alcaftadine 0.25%w/v + Ketorolac Tromethamine 0.4%w/v eye drops (Vide Protocol No. APL/CT/17/05, Version No. 01, dated 22.12.2017) -regarding.

CT No. CT/Drugs/08/2018

Sir,

Please refer to your letter no. APL/DRA/DCGI/18/53 dated 24.01.2018 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 **APL/CT/17/05, Version No. 01, dated 22.12.2017** submitted to this Directorate.

1. Dr. Vupputuri Venkata Lakshmi Narasimha Rao, Kings George Hospital, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh.
2. Dr. Sudhir Kumar Garg, Maharaja Agresen Hospital, Punjabi Bagh, New Delhi-110026.
3. Dr. B. Kantha Sree, Dept. of Ophthalmology, Gandhi Hospital, Musheerabad, Secunderabad-500003.
4. Dr. A. Tarakeswara Roa, Dept. of Ophthalmology, Rajiv Gandhi Institute of Medical Sciences & RIMS Govt. General Hospital, Srikakulam-532001, Andhra Pradesh.
5. Dr. Jigeesh Nareshbhai Desai, Sanjivani Superspeciality Hospital Pvt. Ltd., 1, New Uday Society, Nr. Sunrise Park, Vastrapur, Ahmedabad-380015, Gujarat.
6. Dr. Shalini Mohan, Department of Ophthalmology, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh.
7. Dr. Srikant Kumar Sahu, LV Prasad Eye Institute, MTC Campus, Patia, Bhubaneswar-751 Odisha.
8. Dr. Aniruddha Maiti, Susrut Eye Foundation & Research Centre, HB-36/A/1, Sector III, Lake City, Kolkata-106.
9. Dr. Kumudini Sharma, Dept. of Ophthalmology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014, U.P.
10. Dr. Sandeep Saxena, Dept. of Ophthalmology, Kings George's Medical University, Shahmina Road, Chowk, Lucknow-226003, U.P.
11. Dr. Daxa Pande, Medilink Hospital Research Centre, Basement Medilink Hospital, Shyamal Cross Road, 132, ft. Ring Road, Satellite, Ahmedabad-380015, Gujarat.
12. Dr. Ajay Kartik Ambade, Arneja Heart and Multispeciality Hospital, 123, Ramdaspeth, Nagpur-440010, Maharashtra.

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.

Yours faithfully,

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

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