

Diary No: 29436
Date: 14.11.17

F. No 12-01/12-DC (Pt-Ajanta)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi - 110002 (India)
New Drugs Division

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

Dated: 20-02-2018

To
M/s Ajanta Pharma Ltd.,
Plot No. 43 AB & 44 BCD
Government Industrial Estate,
Charkop, Kandivali (W),
Mumbai-400 067

Subject: Permission for conducting a clinical study entitled, "An Open, Prospective, Non-comparative, Multicenter, Phase IV study to evaluate the Safety and Tolerability of Februric (Febuxostat) Tablets 40mg/80 mg/120 mg in subjects with chronic Hyperuricemia".

CT NOC No.CT/ND/06/2018

Reference: Your application no.APL/DRA/DCGI/17/694, dated- 10-11-2017 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 supervision of the following investigators and as per the **Protocol No: APL/PMS/15/01, Version No: 03, Dated 21.08.2017** submitted to this Directorate.

S.No	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. A. Appalaraju Rajiv Gandhi Institute of Medical Sciences & RIMS, Govt. General Hospital, Srikakulam, Andhra Pradesh-532001	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS, Govt. General Hospital, Srikakulam, Andhra Pradesh-532001 ECR/492/Inst/AP/2013/RR-16
2.	Dr. Satyen Dobhada KMRF's Nikop Hospital, Ring Road, Phaltan, dist.- Satara, Maharashtra-415523	KMRF's Nikop Institutional Ethics Committee, Nikop Hospital, Ring Road, Phaltan, dist.- Satara, Maharashtra-415523 ECR/260/Inst/MH/2013
3.	Dr. Kapadia Kalpesh Kantilal B. J. Medical & Civil Hospital, Dept. of Urology, Asarwa, Ahmedabad, Gujrat-380016.	Institutional Ethics Committee, B. J. Medical & Civil Hospital, Office of Medical Superintendent, Asarwa, Ahmedabad, Gujrat-380016 ECR/72/Inst/GJ/2013/RR-16

4.	Dr.Ashok Kumar Gupta Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi- 110026	Institutional Ethics Committee, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi-110026. ECR/745/Inst/DL/2015
5.	Dr. Vipul Vasantrao Chakurkar Sassoon General Hospitals, Jay Praksh Narayan Road, near Pune railway station, Pune- 411001, Maharashtra	Institutional Ethics Committee of B. J.Govt. College and Sassoon General Hospital, Dept. of Pharmacology, B. J. Govt. Medical College, Sassoon Road, Pune-411001 ECR/280/Inst/Maha/2013/RR-16
6.	Dr. Nandita Choudhury Down Town Hospital, G. S. Road, Dispur, Guwahati- 781006, Assam	Ethics Committee,Down Town Hospital,6 th Flooe, 1 st Building G. S. Road, Dispur, Guwahati-781006, Assam ECR/549/Inst/AS/2014/RR-17
7.	Dr. Geeta Sagar seth Grant Govt. Medical College & Sir J. J Group of Hospitals, LT Road, Mumbai	Institutional Ethics Committee, Grant Govt. Medical College & Sir J. J Group of Hospitals, LT road, Byculla, Mumbai- 400008 ECR/382/Inst/MH/2013/RR-16
8.	Dr. Sanjeev Kumar Sharma Dept. of Nephrology, SMS Medical College & Attached Hospitals, JLN Marg, Jaipur- 302004	Ethics Committee,SMS Medical College & Attached Hospitals, First Floor, Dhanvantri OPD Block, JLN Marg, Jaipur-302004 ECR/26/Inst/RJ/2013/RR-16
9.	Dr. H. Krishna Moorthy Lourdass Hospital, Panchalam, Kochi-682012	Ethics Committee,Lourdass Hospital, Ernakulam, Cochine, Kerala-682012 ECR/482/Inst/KL/2013/RR-16
10.	Dr. Dalal Saurin Pinakin GCS Medical College, Hospital & Research Centre, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad- 380025	Ethics Committee, GCS Medical College, Hospital & Research Centre, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad- 380025. ECR/339/Inst/GJ/2013/RR-16
11.	Dr. Samir Govil Post Graduate Department of Medicine, GSVM Medical College, Swaroop Nagar, Kanpur-208002	Ethics Committee, GSVM Medical College, Principal Office, Swaroop Nagar, Kanpur-208002. ECR/680/Inst/UP/2014

12.	Dr. Mallikarjun S. Karishetti KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi- 590010	Institutional Ethics Committee, KLE University, JN Medical College, Nehru Nagar, Belagavi-590010. ECR/211/Inst/KA/2013/RR-16
13.	Dr. S. N Sankhwar King George Medical University, Lucknow-226003	Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George Medical University, Lucknow-226003 ECR/262/Inst/UP/2013/RR-16
14.	Dr. Arvind Gupta MLN Medical College, Allahabad, UP- 211001	Institutional Ethics Committee, MLN Medical College, Allahabad, UP- 211001. ECR/922/Inst/UP/2013/RR-16
15.	Dr. Anurag Singh, Jeevan Jyothi Hospital & Research Centre, 162, Bai ka Bagh, Lowther Road, Allahabad, UP- 211003	Institutional Ethics Committee and Independent Review Board, Jeevan Jyothi Hospital & Research Centre, 162, Bai ka Bagh, Lowther Road, Allahabad, UP- 211003 ECR/285/Inst/UP/2017
16.	Dr. Deepak Dewan Ajanta Research Centre, Ajanta Hospital & IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow-226005	Institutional Ethics Committee, Ajanta Research Centre, Ajanta Hospital & IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow- 226005 ECR/611/Inst/UP/2014/RR-17

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

- 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.
- Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.
- Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.
- 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) 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 to be conducted by an Investigator 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, 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.

- m) The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- n) 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.
- o) 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.

Yours faithfully,



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

