F. No. CT/18/000087
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)

FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
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File No: CT/18/000087

To,

M/s. Axis Clinicals Limited,
1-121/1, Miyapur, Hyderabad - 500 049.

Subject: Clinical trial titled "A randomized, multiple-dose, double blind, placebo-controlled, parallel group, sequential design, multicentric study to evaluate efficacy and safety of Beclomethasone Dipropionate Metered Dose Inhaler (Inhalation Aerosol) (0.04mg/ INH) in male and/or female subjects with Asthma [Group I (Test): Beclomethasone Dipropionate 0.04 mg/ INH; Group II (Reference): QVAR® 40 mcg (Beclomethasone dipropionate HFA); and Group III: Placebo]"– regarding.

Reference: Your Application No. GCT/Form44/FF/2018/11869 (GCT/84/18) dated 29/November/18.

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 investigators mentioned below and as per the **Protocol No: CR176-17 Protocol Version 1.0, dated 13/November/2018** submitted to this Directorate.

1. Dr. Anurag Agrawal, Sai Baba Nursing Home, Opp, Vijeta Complex New Rajendra Nagar, Raipur-492001.
2. Dr. Arti Shah, Sumandeep Vidyapeeth & Dhiraj General Hospital, At & Po Piparia, Ta Waghodia, Vadodara, 391760, Gujarat, India.
3. Dr. Atul Patel, Amena Khatun General Hospital, Sarkhej Road, Ahmedabad-380055, Gujarat, India.
4. Dr. Deepak B. Varade, Asian Institute of Medical Science, P-72 Milap Nagar, Dombivili (E) M.I.D.C, 421203.
5. Dr. Duraikannan Paramasivan, Sudha Hospitals, 162, Perundurai Road, Erode-638011.
6. Dr. Gopal Raval, Dr. Jivraj Mehta Smarak Health Foundation, Bakeri Medical Research Center, Rutubhai Adani Arogyadham, Dr. Jivraj Mehta Marg, Ahmedabad-380007.
7. Dr. Gautam S, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka.
8. Dr. Hemant Kumar, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, 226010.

9. Dr. Jayesh Shah, Hi-Tech Multispeciality Hospital, Sector 3-D, Plot No. 1180, Gh Road, Nr. Gh-11/2 Bus Stand, Gandhinagar, Gujarat-382003.
10. Dr.Jitendra Anand, Kanoria Hospital & Research Centre, Airport-Gandhinagar Highway, Vil: Bhat, Gandhinagar-382428, Gujarat, India.
11. Dr. Kuntal Shah, Bodyline Hospitals, Opp. Annapurna Hall, Near Dev Status, New Vikas Gruh Road, Paldi, Ahmedabad-380007, Gujarat, India.
12. Dr. Mahavir Satishchand Bagrecha, Shree Hospital, Siddharth Mansion, Nagar Road, Yerwada, Pune-411006, Maharashtra, India.
13. Dr. Micky Patel, Lotus Multispeciality Hospital, Room No. 02, 2nd Floor, Lotus Multispeciality, Hospital, Beside Swastik School, Motera, Stadium Road, Motera, Ahmedabad-380005.
14. Dr. Boyilla Nagaraju, St. Therasa's Hospital, Sanath Nagar, Hyderabad-500018, Telangana State.
15. Dr. Nikalje Rajkumar Gautam, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India.
16. Dr. Sandeep Katiyar, Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh-208002, India.
17. Dr. Sandep Kumar Gupta, M.V. Hospital and Research Centre, 314/30, Mirza Mandi, Chowk, Lucknow-226003, UP, India.
18. Dr. Shayam Narain Gupta, 2/4, Kathauta Chauraha, Nikat Fire Station, Viraj Khand Road, Vastu Khand, Gomti Nagar, Lucknow, Uttar Pradesh-226010.
19. Dr. Shrikant Vishnu Deshpande, Ashirwad Hospital and Research Centre, Maratha Section, Near Jijamata Udyan, Ulhasnagar-4, Maharashtra, India.
20. Dr. Sunil Kumar Mahavar, Department of Medicine, SMS Hospital, JLN Marg, Jaipur-302004, Rajasthan India.
21. Dr. Vineet Kumar Shukla, KRM Hospital & Research Centre, 3/92-93, Vijayant khand, Gomtinagar, Lucknow-226010.

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 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 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.

k. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials 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.

l. 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.

m. 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,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
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Date: 2019.02.08 15:29:48 +05'30'

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