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F. No 12-203/08-DC (Pt-Phase IV)
Government of India

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Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi – 110002 (India)
New Drugs Division

Dated: 01 OCT 2018

To,
M/s. Zuventus Healthcare Ltd.
Emcure House, T-184, M.I.D.C
Bhosari, Pune-411026

Subject: An Open-label, Non-comparative Phase-IV study to evaluate the efficacy, safety and tolerability of Tulobuterol Transdermal Patch-0.5/1/2 mg (Tuloplast™) in patients with asthma or COPD - regarding:

Reference: Application No. ZUVT/Tulobuterol_patch/July_18/05 dated 03.08.2017.

CT NOC No. CT/ND/46/2018

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: ZUV/TULO/02/2016, Version No: 03, dated 22.06.2018** submitted to this Directorate.

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Rajendra Kumar Jenaw M.B.B.S., M.D. (Tuberculosis and Respiratory Diseases) Institute of Respiratory Diseases, SMS Medical College, Jaipur	Institutional Ethics Committee SMS Medical College & Attached Hospital, JLN Marg, Jaipur-302004 EC Registration no: ECR/26/Inst/RJ/2013/RR-16
2.	Dr. Surajit Chatterjee M.B.B.S., M.D. (Pulmonary Medicine) Institute of Post-Graduate Medical Education and Research, 244, A.J.C. Bose Road, Kolkata, West-Bengal 700020	IPGME & R Research Oversight Committee Committee, College buildings, 5th Floor, Institute of post graduate Medical Education and research, 244 AJC Bose Road Kolkata-700020 EC Registration no: ECR/35/Inst/WB/2013/RR-16

3.	Dr. Anand Kumar M.B.B.S., M.D. (Tuberculosis and Respiratory Diseases) Department of Pulmonology, G.S.V.M Medical College, Near Rawatpur Crossing, Kanpur – 208002	Ethics Committee, G.S.V.M Medical College Principal office GSVM Medical College, Swaroop Nagar, Kanpur-208002, U.P-India EC Registration no: ECR/680/Inst/UP/2014
4.	Dr. Hansraj Alva M.B.B.S., M.D. Medical Director, Vinaya Hospital and Research Centre Mangalore	Ethics Committee Vinaya Hospital and Research Centre Karangalpady Mangalore 575003 EC Registration no: ECR/664/Inst/KA/2014/RR-17
5.	Dr. Hemant Tahilramani M.B.B.S., M.D. (Pediatrics) Jaipur National University, Institute of Medical Sciences and Research, Jagatpura, Jaipur 302017	Institutional Ethics Committee, Jaipur National University, Institute of Medical Sciences and Research, Jagatpura, Jaipur-302017 EC Registration no: ECR/905/Inst/RJ/2017
6.	Dr. A.D. Nageswari M.B.B.S., D.T.C.D., M.D. (Chest) Professor and HOD, Pulmonary Medicine, Tagore Medical College and Hospital	Tagore Medical College and Hospital, Rathinamangalam Chennai – 600127 Ethics Committee, Tagore Medical College and Hospital EC Registration no: ECR/634/Inst/TN/2014/RR-17
7	Dr. Rasid Parvez M.B.B.S, M.D (Respiratory medicine) Consultant Janta Hospital, Near water head tank, Amra-Akhri bypass Varanasi 221011	Janta hospital Ethics committee Near water Head Tank, Amara-Akhari bypass, Chunar Road Varanasi-221011 EC Registration no: ECR/839/Inst/UP/2016
8.	Dr. Sanjeev Kumar Verma M.B.B.S., M.D. Assistant professor Department of Pediatrics king George's Medical university, Chowk, Lucknow 226003	Institutional Ethics Committee, Office of Research cell, King George Medical university EC Registration no: ECR/262/Inst/UP/2013/RR-16
9.	Dr. Sakhala Swapnil Suresh M.B.B.S., D.T.C.D., D.N.B. (Pulmologist) Vijan Hospital & Research Centre College Road, Maharashtra Nashik – 422005	Vijan Cardiac and Critical care center Hospital & Research Centre, Vijan Hospital Marg, College Road, Nashik – 422005 EC Registration no: ECR/406/Inst/MH/2013/RR-16

Kindly 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 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.
- 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 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.

Yours faithfully,



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