Nil

File No.FDC/MA/22/000297
Government 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: 15 FEB 2023

To,

M/s. Zydus Healthcare Limited,
Zydus Corporate Park, Scheme No. 63 Survey No. 536,
Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,
S.G. Highway Ahmedabad-382481.

Subject: Permission to conduct Phase III clinical trial with the FDC of Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg metered dose inhalation(Vide protocol no. 22-08, version no. 0.0, dated 26.08.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 01.10.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-108/2022** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

CONDITIONS OF PERMISSION

I. Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;

II. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

   i. Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

   ii. Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

III. In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

IV. The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

V. Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

VI. Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

VII. Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

VIII. Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

IX. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

X. Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

XI. In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

XII. In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

XIII. The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

XIV. Where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

XV. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

XVI. The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

XVII. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

XVIII. The formulation intended to be used in the clinical trial study shall be manufactured under GMP conditions using validated procedures.

XIX. It may kindly be noted that merely granting permission to conduct Clinical trials/Bioavailability or Bioequivalence study with the drug does not convey or imply that, based on the Clinical trial data/ Bioavailability or Bioequivalence study data generated with the drug, permission to market this drug in the country will automatically be granted to you.

XX. **The Inhalation toxicity study should be conducted before initiating the clinical trial study.**

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR ~~INVESTIGATIONAL NEW DRUG~~

Permission no.: FDC-CT-06-108/2022

1. The Central Licencing Authority hereby permits **M/s. Zydus Healthcare Ltd. Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj Gandhinagar, Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat, India, Gujarat–382481, Telephone No.: 07948040000 FAX: 07948041500** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. 22-08, version no. 00, dated 26.08.2022)** in the below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date: .....

15 FEB 2023

Central Licencing Authority

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg metered dose inhalation
Therapeutic class:	Long-acting beta2-adrenergic agonist (LABA) and Long-acting muscarnic antagonist(LAMA)
Dosage form:	Metered dose inhalation
Composition:	Each actuation Delivers contains: Vilanterol Trifenatate eq. to Vilanterol .... 12.5mcg Glycopyrrolate IP eq. to Glycopyrronium 25mcg
Indications:	Indicated as a maintenance treatment for patients with chronic obstructive pulmonary disease (COPD).

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

Annexure-A

Permission no.: FDC-CT-06-108/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr.Subhasis Mukherjee	Department of Respiratory Medicine, College of Medicine & Sagore Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata – 700058, West Bengal	Institutional Ethics Committee, Department of Respiratory Medicine, College of Medicine & Sagore Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata – 700058, West Bengal (ECR/1210/Inst/WB/2019/RR-22)
2	Dr. Raja Bhattacharya	Medical College and Hospital, 88 College Street Kolkata-70003, India	Institutional Ethics Committee for Human Research, Medical College and Hospital Kolkata,88 College Street Kolkata-70003, India ECR/287/Inst/WB /2013/RR-19
3	Dr. Ankit Kumar	Department of Respiratory Medicine, King George's Medical University, Shahmeena Road, Chowk, Lucknow- 226003, Uttar Pradesh	Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow- 226003, Uttar Pradesh (ECR/262/Inst/UP/2013/RR-19)
4	Dr. Jyothi Hattiholi	Department of Respiratory Medicine, Jawaharlal Nehru Medical College and K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi – 590010, Karnataka	Institutional Ethics Committee, KLE University, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi – 590010, Karnataka (ECR/211/Inst/KA/2013/RR-19)
5	Dr. Vijaykumar Barge	Department of Medicine, RCSM Government Medical College and CPR Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur – 416012, Maharashtra	RCSMGMCIEC2 RCSM Government Medical College and CPR Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur – 416012, Maharashtra (ECR/703/Inst/MH/2015/RR-20)
6	Dr.Ravi Koppula	Department of Pulmonology, Government Medical College and Government General Hospital, Srikakulam – 532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College and Government General Hospital, Srikakulam – 532001, Andhra Pradesh (ECR/492/Inst/A P/2013/RR-20)
7	Dr. Manish Kumar Jain	Maharaja Agrasen Superspecialty Hospital Central Spine, Agrasen Aspatal Marg, Sector-7 Vidyadhar Nagar, Jaipur, Rajasthan -302039	Institutional Ethics Committee, Maharaja Agrasen Superspecialty Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur, Rajasthan -302039 ECR/1222/Inst/RJ/2019
8	Dr. Rajkumar Gautam Nikalje	Lifepoint Multispecialty Hospital, 145/1, Mumbai-Bangalore Highway. Near Hotel Sayaji, Bhumkar	Lifepoint Research-Ethics Committee Life Point Mutispecialty Hospital, 145/1, Mumbai-Bangalore

		Chowk, Wakad, Pune - 411057, Maharashtra	highway Near Hotel Sayaji, Wakad, Pune – 411057, Maharashtra (ECR/751/Inst/MH/2015/RR-21)

Place: New Delhi

Date: .....

15 FEB 2023

Central Licencing Authority

Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002