Nil

File No.FDC/CT/22/000022
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:
02 AUG 2022

To,

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

Subject: **Permission to conduct Phase IV clinical trial with the FDC of Glycopyrrolate IP 9.0mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8mcg + Budesonide IP 160mcg per actuation deliver (Vide protocol no. 22-05, version no. 00, dated 03.05.2022)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-04 on dated 14.05.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-59/2022** 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:

III. 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;

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-06-59/2022

1. The Central Licencing Authority hereby permits **M/s. Zydus Healthcare Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat (India)–382481, Telephone No.: 091-079-48040978, FAX: 091-079-48040000** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. 22-05, version no. 00, dated 03.05.2022)** 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: 02 AUG 2022

Central Licencing Authority

Stamp

Dr. V. G. [illegible]
Drugs Controller [illegible]
Dte. General of [illegible]
Ministry of He[illegible]
FDA Bhawan, Ko[illegible]
New Delhi-[illegible]

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Glycopyrrolate, Formoterol Fumarate and Budesonide Inhalation 9mcg, 4.8mcg and 160mcg
Therapeutic class:	Bronchodilators
Dosage form:	Inhaler
Composition:	Each actuation delivers: Glycopyrrolate IP .... 9.0mcg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate .... 4.8mcg Budesonide IP .... 160mcg suspended in inert propellant .... q.s.
Indications:	For the treatment of 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-06-59/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	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/RR-22
2	Dr. Sarat Kumar Behera	Kanungo Institute of Diabetes Specialities, 1120 Dumduma Bhubaneswar Khordha Orissa-751019	KIDS Ethics Committee, Kanungo Institute of Diabetes Specialities, 1120 Dumduma Bhubaneswar Khordha Orissa-751019 ECR/1132/Inst/OD/2018/RR-22
3	Dr. Nikalje Rajkumar Gautam	Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra ECR/751/Inst/MH/2015/RR-21
4	Dr. Ravi Koppula	Government Medical College & Government General Hospital (Old RIMSGGH), Srikakulam, Andhra Pradesh-532001	Institutional Ethics Committee, Government Medical College & Government General Hospital, Srikakulam, Andhra Pradesh-532001 ECR/492/Inst/AP/2013/RR-20

Place: New Delhi

Date: .....
02 AUG 2022

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