Nil

File No. FDC/MA/21/000147
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-232369
Fax No. :011-232369

FDA Bhawan, Kotla R
New Delhi-110

Dated:

13 SEP 2021

To,

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.

Subject: **Permission to conduct Phase III clinical trial with the FDC of Indaca Maleate eq. to Indacaterol + Budesonide IP (75mcg + 200mcg & 150m 400mcg) dry powder for inhalation (Capsules) (Vide protocol no. 2 version no. 00, dated: 18.06.2021)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on c 30.06.2021 please find enclosed herewith the "permission to conduct clinical trial study of drug" bearing no. **CT-06-146/2021** under the provision of Drugs and Cosmetics Act and R The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faith

(Dr. V. G. Son
Drugs Controller General (Ir

CONDITIONS OF PERMISSION

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

II. Where a clinical trial site does not have its own Ethics Committee, clinical trial at tha may be initiated after obtaining approval of the protocol from the Ethics Committe another trial site; or an independent Ethics Committee for clinical trial constitute accordance with the provisions of rule 7:
   i. Provided that the approving Ethics Committee for clinical trial shall in such cas 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 si the bioavailability and bioequivalence centre, as the case may be, shall be loc 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 details of the same shall be submitted to the Central Licensing Authority prior to see approval of another Ethics Committee for the protocol for conduct of the clinical trial a same site;

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

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.: CT-06-146/2021

1. The Central Licencing Authority hereby permits **M/s. Zydus Healthcare L Zydus Corporate Park, Scheme No. 63, Survey No. 536, Kh (Gandhinagar), Nr, Vaishnodevi Circle, S.G. Highway, Ahmedabad-382 Gujarat, India.** (Name and full address with contact details of the applicant conduct clinical trial of the new drug or investigational new drug as per prot number **(Vide protocol no. 21-05, version no. 00, dated: 18.06.2021** in below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmet Act, 1940.

Place: New Delhi

Date: .....

13 SEP 2021

Central Licencing Authori

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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Indacaterol Maleate eq. to Indacaterol + Budesonide (75mcg + 200mcg & 150mcg + 400mcg) dry powder inhalation (Capsules)
Therapeutic class:	Corticosteroid and Bronchodilator
Dosage form:	Dry Powder For Inhalation (Capsules)
Composition:	Indacaterol Maleate eq. to Indacaterol + Budesonide (75mcg + 200mcg & 150mcg + 400mcg) dry powder inhalation (Capsules)
Indications:	In patients with chronic obstructive pulmonary disease

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.: CT-06-146/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Raghumanda Sunil Kumar	Professor and HOD, Department of Pulmonology, Government Medical College & Government General Hospital, Old RIMSGGH, Srikakulam, Andhra Pradesh- 532 001, India	Institutional Ethics Committee Government Medical College & Government General Hospital, Srikakulam, Andhra Pradesh - 532 001, India (ECR/492/Inst/AP/2013/RR-20)
2	Dr Neeraj Gupta	Professor & Head, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan (ECR/1156/Inst/RJ/2018)
3	Dr Manish Kumar Jain	Consultant Pulmonologist Maharaja Agrasen Superspeciality Hospital, Central Spine Sector No. - 7 Vidhyadhar Nagar, Jaipur, Rajasthan–302039	IEC Maharaja Agrasen Hospital situated at Maharaja Agrasen Superspeciality Hospital Central Spine Agrasen Aspatal Marg Sector 7 Vidhyadhar Nagar Jaipur, Rajasthan (ECR/1222/Inst/RJ/2019)
4	Dr. Gautam S	Consultant Pulmonologist, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi (Belgaum) – 590002, Karnataka	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi– 590002, Karnataka (ECR/1242/Inst/KA/2019)
5	Dr. Nikalje Rajkumar Gautam	Consultant Pulmonologist Lifepoint Multispecialty Hospital, 145/1 ,Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057,Maharashtra,India.	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1,Mumbai Bangalore Highway, Near Hotel Sayaji,Wakad,Pune 411057, Maharashtra,India (ECR/751/Inst/MH/2015/RR-21)
6	Dr. Jitendra Singh Kushwaha	Consultant Physician, Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, UttarPradesh 208002	Ethics Committee, Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002 (ECR/1017/Inst/UP/2017/RR-21)

Place: New Delhi

Date: .....

13 SEP 2021

Central Licencing Authority

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Dr. V. G. SOMANI
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