

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:

To,

M/s. Theon Pharmaceuticals Ltd.,
Village Saini Majra, Tehsil Nalagarh,
Distt. Solan, Baddi, Himachal Pradesh-174101.

31 MAY 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Teneligliptin Hydrobromide hydrate IP eq. to Teneligliptin (5mg + 20mg & 10mg + 20mg) film coated tablets (Vide protocol no. SB-IND-CT-042, version no. 1.0, dated: 10.03.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 22.03.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-49/2022** 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 Licencing 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;

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

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUGPermission no.: **FDC-CT-06-49/2022**

1. The Central Licencing Authority hereby permits **M/s. Theon Pharmaceuticals Ltd., Village Saini Majra, Tehsil Nalagarh, Distt. Solan, Baddi, Himachal Pradesh-174101, Telephone no. 01795669200, Fax: 01795669200** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. SB-IND-CT-042, version no. 1.0, dated: 10.03.2022)** 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:

31 MAY 2022

Annexure:

Details of new drug or investigational new drug:

Central Licencing Authority

Stamp

डॉ. वी. जी. सोमानी

औषधि महानियंत्रक (भारत)

स्वास्थ्य सेवा महानिदेशालय

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.

नई दिल्ली-110002

Names of the new drug or investigational new drug:	Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Teneligliptin Hydrobromide hydrate IP eq. to Teneligliptin (5mg + 20mg & 10mg + 20mg) film coated tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each film coated tablets contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Teneligliptin Hydrobromide hydrate IP eq. to Teneligliptin (5mg + 20mg & 10mg + 20mg)
Indications:	In patients with type 2 diabetes mellitus inadequately controlled on earlier Metformin containing mono therapy.

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-APermission no.: **FDC-CT-06-49/2022**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Maghavendra Kumar	Vidhya Hospitals & Trauma Centre, Harikansgadi Mohanlalganj Raebareli Road, Lucknow-226301, U.P.	Vidhya Hospital and Trauma Centre Ethics Committee, Room No. 06, Ground Floor, Vidhya Hospital & Trauma Centre, Harikansgadi Mohanlalganj Raebareli Road, Lucknow-226301, U.P. ECR/1579/Inst/UP/2021
2	Dr. Praveen Kumar Devarbhavi	Subbaiah Institute of Medical Sciences, NH-13, HH Road Purle, Shivamogga Karnataka-577202	Ethics Committee of Subbaiah Institute of Medical Sciences, HH Road Purle, Shivamogga Karnataka-577202 ECR/1358/Inst/KA/2020
3	Dr. Suman Kumar Roy	Dept of Com. Medicine College of Medicine & JNM Hospital, Kalyani, Nadia, West Bengal-741235	IEC of College of Medicine & JNM Hospital, IEC of COM&JNMH, Kalyani, Nadia, West Bengal-741235 ECR/674/Inst/WB/2014/RR-21
4	Dr. Syed Umer Quadri	MGM Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra	MGM Ethics Committee for research on Human Subjects (MGM-ECRHS), Dept. of Pharmacology MGM Compas, N-6, CIDCO, Aurangabad-431003, Maharashtra ECR/518/Inst/MH/2014/RR-20

Place: New Delhi

Date:

31 MAY 2022

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