सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi – 110002, India
Phone No.:91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/22/000099

To

M/s Lotus Labs Pvt. Ltd.,
10th Floor, D Wing, Tower II, Seawoods Grand Central,
Plot No. R1, Sector – 40, Seawoods Railway Station,
Navi Mumbai – 400706, Maharashtra, India
Tel: +91-(0)-22-6282-9700, Email: lotus.regulatory@teva.co.in

Sir,

With reference to your SUGAM application vide F. no. GCT/CT04/FF/2022/33788 (GCT/99/22) dated 08-Sep-2022, please find enclosed herewith the permission in Form CT-06 for conduct of phase III clinical trial titled," **A Multinational, Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy, Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity of TEV-45779 Compared to Omalizumab (XOLAIR®) in Patients With Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria who Remain Symptomatic Despite Antihistamine (H1) Treatment" Protocol Number: TV45779-IMB-30086, Amendment 03 dated 10-May-2022** with a total of up to 100 subjects under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, specifically that: -

1) **the H1-antihistamines (preferably the second generation H1-antihistamines in the approved dosage regimen) should be used as standard care and it shall be uniform across all the study sites in the country**;

2) 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;

3) 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:

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:

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;

4) 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;

5) 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;

6) 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;

7) 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;

8) 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;

9) 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;

10) 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;

11) 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;

12) 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;

13) 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;

14) 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;

15) 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;

16) 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;

17) 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;

18) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

19) merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

20) the permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,



VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba4[illegible], cn=VENUGOPAL G SOMANI

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s Lotus Labs Pvt. Ltd., 10th Floor, D Wing, Tower II, Seawoods Grand Central, Plot No. R1, Sector – 40, Seawoods Railway Station, Navi Mumbai – 400706, Maharashtra, India, Tel: +91-(0)-22-6282-9700, Email: lotus.regulatory@teva.co.in** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: TV45779-IMB-30086, Amendment 03 dated 10-May-2022** in the below mentioned clinical trial sites [As per Annexure]. -
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 _____

VENUGOPAL G SOMANI (Dr. V G Somani)
Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb25574873 2c456d24907 3e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=a97f241aa0c0bba4152252 5ffe602b5074b48e7e8 3f3 3a4e4f1232 5dea4d, cn=VENUGOPAL G SOMANI
Date: 2022.12.16 12:16:16 +05'30'

Drugs Controller General (India)
Central Licencing Authority

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	TEV-45779 (Proposed biosimilar to Omalizumab)
Therapeutic class:	Humanized immunoglobulin G1 (IgG1) / kappa monoclonal antibody (mAb) directed against IgE
Dosage form:	Pre-filled syringe containing solution for SC injection [150mg/mL (1ml)]
Composition:	Each PFS of TEV-45779 contains 150 mg TEV-45779 in 1 mL of solution
Indications:	Chronic Idiopathic Urticaria (CIU) / Chronic Spontaneous Urticaria (CSU)

Annexure:

Details of clinical trial site:

S.No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Sir Ganga Ram Hospital, Department of Dermatology, SRGH Marg, Rajinder Nagar-110060, New Delhi	Ethics Committee, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital, Room no. 1643, 6h floor, Casualty Building, Old Rajinder Nagar-110060, New Delhi	Dr. Rohit Batra
2.	GMERS Medical College and Civil Hospital Sola, SG Highway, Near Gujarat High Court, Ahmedabad, Gujarat-380060	Institutional Ethics Committee, GMERS Medical College and Hospital, Sola Gam Rd, near High Court, Sola, Ahmedabad, Gujarat-380060	Dr. Krina B. Patel
3.	GMERS Medical College and General Hospital, Gotri,Vadodara-390021, Gujarat	Institutional Human Ethics Committee, GMERS Medical College and General Hospital, Gotri,Vadodara-390021, Gujarat	Dr. Sejal P. Thakkar
4.	Nirmal Hospital Pvt. Ltd., Ring Road, Surat-395002, Gujarat	Nirmal Hospital Pvt. Ltd. Ethics Committee, Nirmal Hospital Pvt. Ltd., Ring Road, Surat-395002, Gujarat	Dr. Dipak Amrutbhai Patel
5.	Dr. D.Y. Patil Hospital & Research Centre, Sector-5,Nerul, Navi Mumbai-400706, Maharashtra	Institutional Ethics Committee, D.Y. Patil Medical College, Sector-5,Nerul, Navi Mumbai-400706, Thane, Maharashtra	Dr. Godse Kiran Vasant
6.	Assured Care Plus Hospital, 4th & 5th Floor Star Plus Complex, Lam Road, Opposite to NMC Divisional Office, Near Muktidham Temple, Nashik Road, Nashik-422101, Maharashtra	Yash Society's Sujata Birla Ethics Committee, C/O Sujata Birla Hospital & Medical Research Centre, Opposite to Bytco College, Nashik Pune Highway, Nashik Road, Nashik-422101, Maharashtra	Dr. Vartak Suneel Chandrakant
7.	Kempegowda Institute of Medical Sciences (KIMS Hospital), Department of Dermatology B Block, 2nd floor, Room no 10, KR Road, VV Puram, Bangalore- 56004	KIMS Institutional Ethics Committee, KIMS college, Bsk 2nd stage, Bangalore - 560070	Dr. Nandini A S
8.	KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-590010, Karnataka	Institutional Ethics Committee, KLE University, KLE DR PK Hospital and MRC, Nehru Nagar, Belagavi, Karnataka-590010	Dr. Shivakumar K Patil

9.	M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka	Ethics Committee, M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka	Dr. (Smt.) T K Sumathy
10.	Department of Dermatology, Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara P.O, Kochi - 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara P.O, Kochi-682041	Dr. Vinitha Varghese Panicker

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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA