ND/CT04/FF/2024/41549
Dated: 24.01.2024

Tele No. 91-22-43244324
FAX: 91-22-43244343

F. No. ND/CT/24/000001
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

To
M/s Glenmark Pharmaceuticals Ltd.,
B2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road,
Mumbai, Maharashtra (India) - 400026

Subject: Grant of Permission for conducting Phase IV clinical study entitled "A Phase IV, prospective, single arm, multi-centric study for assessment of Safety and Effectiveness of FDC Lobeglitazone 0.5mg + Glimepiride 1mg in management of Type 2 Diabetes Mellitus (T2DM) in Indian patients (LOBG-G1)" -Regarding.

Sir,

With reference to your Application No. ND/CT04/FF/2024/41549 dated 24.01.2024, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/07/2024** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions as mentioned below.

RAJEEV SINGH RAGHUVANSHI

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Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

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 Licensing 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:

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;

(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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of

receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 Licensing 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 Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) It may kindly be noted that granting permission to conduct Clinical Trial study with the drug doesn't convey or imply that based Clinical Trial data generated with the drug, permission to market this drug will automatically be granted to you.

FORM CT-06

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

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

The Central Licensing Authority hereby permits M/s Glenmark Pharmaceuticals Ltd., B2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai, Maharashtra (India) – 400026, Telephone No.: 2240189999 FAX: 2240189988 E-Mail: kishansingh.kaira@glenmarkpharma.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: GPL/CT/2023/006/IV; Version No. 2.0; Dated 03-Apr-2024** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

Names of the new drug ~~or investigational new drug~~:		**Lobeglitazone Sulfate 0.5mg + Glimepiride 1mg Tablets**
Therapeutic class:		**Antidiabetic**
Dosage form:		Tablets
Composition:		Each uncoated bilayer tablet contains Lobeglitazone Sulfate…..0.5mg Glimepiride……..1mg
Indications:		Indicated an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a thiazolidinedione and sulphonylurea or who have inadequate glycemic control on a thiazolidinedione alone or a sulphonylurea alone.
Details of clinical trial sites-		
Sr. No.	**Name of Principal Investigator & Trial Sites**	**Ethics Committee Name/ Registration Number**
01	Dr. Prabhat Kumar Agrawal S.N Medical College, Agra Near Agra College, Central Library, Agra-282003.	Institutional Ethics Committee S.N Medical College Raja Mandi Near Agra College Agra Central Library, Moti Katra Mantola, Agra, Agra, Uttarpradesh-282003 India **EC Registration No.:** **ECR/1409/Inst/UP/2020**
02	Dr. Vijay Kumar Bhagwan Barge Rajarshee Chhatrapati Shahu Mahraj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara chowk, Bhausinghaji Road, Town hall, Kolhapur, Maharashtra - 416012 India	Rajarshee Chhatrapati Shahu Mahraj Govt. Medical College and Chhatrapati Pramila Raje General Hospital (RCSMGMCIEC2) Building No. 2, Qurter No 3, Room No. 7 Dassara Chowk Kolhapur, Maharashtra - 416007 India **EC Registration No.:** **ECR/703/Inst/MH/2015/RR-20**
03	Dr. Vinod Kumar Kapoor New Leelamani Hospital Pvt Ltd. 14/116,C-I,Parade Chauraha, Civil	Institutional Ethics Committee-Leelamani Hospital, New Leelamani Hospital,14/116 B, C, C-1D, 1 Civil Lines, Kanpur, Uttar Pradesh -

	Lines, Kanpur UP - 208001	208001 India **EC Registration No.:** **ECR/1696/Inst/UP/2022**
04	Dr. Suresh G Bhate Jeevan Rekha Hospital, Near Nagshanti Motor showroom, Veer Chamber, Opp. Civil Hospital, Dr. B.R Ambedkar Road, Belagavi, 590002	Ethics Committee Jeevan Rekha Hospital, Jeevan Rekha Hospital, Dr. B.R Ambedkar Road Opp. Civil Hospital Belagavi, Belagavi (Belgaum) Karnataka - 590002 India **EC Registration No.:** **ECR/1242/Inst/KA/2019/RR-22**
05	Dr. Imran Khan Department of General Medicine, Princess Durrushehvar Children's & General Hospital, Purani Haveli, Hyderabad-500 002, Telangana, India	Institutional Ethics Committee - Princess Durrushehvar Children's & General Hospital, # 22-3-660/A, Purani Haveli, Hyderabad-500 002, Telangana, India. **EC Registration No.:** **ECR/1612/Inst/TG/2021**
06	Dr. Vijay Kumar All India Institution of Medical Science,Patna- Aurangabad Rd, Phulwari Sharif, Patna-801507, Bihar, India	Institue Ethics Committee-AIIMS patna Phulwarisharif patna Bihar-801507 **EC Registration No.:** **ECR/1387/Inst/BR/2020**

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.

RAJEEV SINGH RAGHUVANSHI

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New Delhi

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority
Stamp