



Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
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New Delhi - 110002 (Delhi)
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File No. BIO/CT/24/000040

Dated 29-11-2024

To,

M/s Levim Lifetech Private Limited,
Ticel Biopark-II, 501-505 CSIR Road,
Taramani Chennai (India) – 600113

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled – "A Phase IV, Open Label, Prospective, Multi-Center Study to Evaluate the Safety and Efficacy of Liraglutide Biosimilar in Patients with Type 2 Diabetes Mellitus" as per Protocol No.: NV-05-1575-2023 Version 2.0 Amendment 2 dated 16.09.2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/42174 dated 29.03.2024

Sir,

With reference to your application No.: BIO/CT04/FF/2024/42174 dated 29-MAR-2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (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.

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 Levim Lifetech Private Limited, Tichel Biopark-II, 501-505 CSIR Road, Taramani Chennai (India) – 600113 to conduct Phase IV clinical trial entitled – **"A Phase IV, Open Label, Prospective, Multi-Center Study to Evaluate the Safety and Efficacy of Liraglutide Biosimilar in Patients with Type 2 Diabetes Mellitus"** as per Protocol No.: **NV-05-1575-2023 Version 2.0 Amendment 2 dated 16.09.2024**" in the below mentioned clinical trial sites.

2. Details of 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.
4. It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 29-Nov-2024

RAJEEV SINGH
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.12.02 15:41:00 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:**Details of new drug or investigational new drug:**

| | | | |
|--|--|-------------------------|-----------------|
| Names of the new drug or investigational new drug: | Liraglutide 6.0 mg/ml solution for injection (in prefilled pen) (r-DNA Origin) | | |
| Therapeutic class | Antidiabetic | | |
| Dosage form: | Solution for Injection in 3 ml cartridge (18mg/3mL) | | |
| Composition: | Each 1 ml contains | | |
| | Name of Ingredients | Quantity (mg/mL) | Function |
| | Liraglutide drug Substance In-house | 6.0 | API |
| | Phenol Crystalline, USP/IP | 5.5 | Preservative |
| | Disodium hydrogen phosphate dehydrate USP/BP | 1.42 | Buffer |
| | Glycerol BP/IP | 16 | Tonicity agent |
| | Hydrochloric acid BP/Ph.Eur | q.s. | pH adjustment |
| | Sodium hydroxide BP/Ph.Eur | q.s. | pH adjustment |
| | *Sodium hydroxide and hydrochloric acid used to adjust pH to 7.2 -7.5 | | |
| Indications: | For the treatment of Type II Diabetes Mellitus | | |

Details of clinical trial site:

| S. No. | Name and Address of Clinical Trial Site | Ethics Committee Details | Name of Principal Investigator |
|--------|--|--|--------------------------------|
| 1. | Nirmal Hospital Pvt. Limited, Sagrampura Ring Road, Surat-395002, Gujarat, India | Institutional Ethics Committee, Nirmal Hospital Private Limited, Ring Road, Surat -395 002, Gujarat EC Reg. No.: ECR/390/Inst/GJ/2013/RR-19 | Dr. Piyush Desai |
| 2. | Crescent Hospital & Heart Center, 1 st Lane, Near Lokmat Square, Behind Old Mount Carmel School, Dhantoli, Nagpur, Maharashtra 440012 | Institutional Ethics Committee, Crescent Hospital & Heart center 1st Lane, Near Lokmat Square, Behind Old Mount Carmel School, Dhantoli, Nagpur, Maharashtra 440012 EC Reg No. ECR/682/Inst/MH/2014/RR-21 | Dr. Kashif Sayed |
| 3. | DEC-Health Care Hospital 16/2/219, Pogathota, Nellore, Andhra Pradesh - 524001, India. | Institutional Ethics Committee, DEC-Health Care Hospital 16/2/219, Pogathota, Nellore, Andhra Pradesh -524001, EC Reg No: ECR/453/Inst/AP/2013/RR-19 | Dr. Rammohan M.V |
| 4. | SSG Hospital, Medical college Baroda, Jail Road (Indira Avenue), Anandpura, Vadodara-390001, Gujarat | Institutional Ethics Committee, SSG Hospital, Medical college Baroda, Jail Road (Indira Avenue), Anandpura, Vadodara-390001, Gujarat. EC Reg No. ECR/85/INST/GJ/2013/RR/19 | Dr. Keyur Brahme |