सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation(Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/21/000003 Dated: 05-Sep-2022

To,

M/s Hinge Clinica Pvt. Ltd,
Cyber Towers, Quadrant-4,
Second Floor, Hitech City, Madhapur,
Hyderabad, Telangana (India) – 500081.

Subject: Application for grant of permission to conduct Phase III clinical trial entitled –" A Prospective, Multi-center, Randomized, Double-blind, Parallel-group, Active-controlled,Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Regenix Biosciences Limited Human Insulin Basal Bolus(Investigational drug)-Jusline 30/70 with Eli Lilly's bacteria based Human Insulin Basal Bolus (Reference drug)-Humulin 30/70 in Type I and Type II Diabetes " as per Study protocol JUSL30/70-0220 version no 02 dated 16.08.2022– regarding

Ref.:Your Application No. BIO/CT04/FF/2020/19709 dated 04-01-2021

Sir,

With reference to your Application No. BIO/CT04/FF/2020/19709 dated 04-01-2021, 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) The firm should submit the application for permission to import the test product and reference product for CT purpose as per New Drugs and Clinical Trials Rules 2019

(II) The firm should submit the insurance certificate mentioning the protocol title and number before initiation of the study and submit the same to this office.

(III) The firm shall submit revised investigator undertaking in original, mentioning the current approved protocol details before initiation of the clinical trial

(IV) 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;

(V) 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;

(VI) 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;

(VII) 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;

(VIII) 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;

(IX) 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;

(X) 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;

(XI) 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;

(XII) 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;

(XIII) 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;

(XIV) 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 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;

(XV) 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 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;

(XVI) 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 authorised 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;

(XVII) 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;

(XVIII) 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;

(XIX) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XX) 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.

Yours faithfully,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

File. No. BIO/CT/21/000003

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 Licencing Authority hereby permits M/s Hinge Clinica Pvt. Ltd,Second Floor, Quadrant-4, Cyber Towers, Hitech City,Madhapur,Hyderabad, Telangana (India) – 500081, to conduct clinical trial of the new drug or investigational new drug study titled “A Prospective, Multi-center, Randomized, Double-blind, Parallel-group, Active-controlled,Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Regenix Biosciences Limited Human Insulin Basal Bolus(Investigational drug)-Jusline 30/70 with Eli Lilly’s bacteria based Human Insulin Basal Bolus (Reference drug)-Humulin 30/70 in Type I and Type II Diabetes ” as per Study protocol JUSL30/70-0220 version no 02 dated 16.08.2022 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.

Place: New Delhi
Date: 05.09.2022

VENUGOPAL G SOMANI

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

Digitally signed by VENUGOPAL G SOMANI
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Date: 2022.09.05 17:17:31 +05'30'

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug</td><td>Insulin Injection,Biphasic Isophane Ph.Eur 100IU/ml(30% soluble insulin/70% isophane insulin)</td></tr>
<tr><td>Therapeutic class</td><td>Anti-diabetic</td></tr>
<tr><td>Dosage form:</td><td>Solution for injection</td></tr>
<tr><td>Composition:</td><td>
<table>
<tr><th>Name of Ingredient</th><th>Quantity/ per ml</th></tr>
<tr><td>*Insulin human Ph.Eur(Insulin, Human of r-DNA origin)</td><td>100 IU</td></tr>
<tr><td>m-cresol Ph.Eur</td><td>1.60mg</td></tr>
<tr><td>Liquified phenol Ph.Eur</td><td>0.73 mg</td></tr>
<tr><td>Glycerin Ph.Eur</td><td>16.0mg</td></tr>
<tr><td>Zinc oxide Ph.Eur</td><td>0.011mg</td></tr>
<tr><td>Protamine sulfate Ph.Eur</td><td>0.241mg</td></tr>
<tr><td>Dibasic sodium phosphate Ph.Eur</td><td>3.78 mg</td></tr>
<tr><td>Hydrochloric acid(10%) Ph.Eur</td><td>q. s.</td></tr>
<tr><td>Sodium hydroxide(10%) Ph.Eur</td><td>q.s</td></tr>
<tr><td>Water for injection</td><td>q.s to 1ml</td></tr>
<tr><td colspan="2">Note: *Human Insulin crystals using 1% overage</td></tr>
</table>
</td></tr>
<tr><td>Indications:</td><td>Treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis</td></tr>
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Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	King George Hospital, Visakhapatnam - 530002	Institutional Ethics Committee, King George Hospital, Visakhapatnam – 530002 EC Reg. No. ECR/197/Inst/KGH/2013/RR-16	Dr. B. L. N. Prasad
2	Govt. Medical College and Govt. General Hospital (Old RIMSGGH), Srikakulam532001	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001 EC Reg. No. ECR/492/Inst/AP/2013/RR-16	Dr. K. Sunil Naik
3	Nirmal Hospital Pvt Ltd, Ring road, Surat -395002, Gujarat	Nirmal Hospital Pvt Ltd Ethics Committee, Ring road, Surat - 395002, Gujarat. EC Reg. No.	Dr .Piyush Desai

		ECR/390/Inst/GJ/2013/RR-16	
4	Vijaya Super speciality Hospital, Raghava Cine Complex Rd, Pogathota, Nellore – 524001	Vijaya Ethics Committee, Vijaya Super speciality Hospital, Raghava Cine Complex Rd, Pogathota, Nellore -524001 EC Reg. No. ECR/453/Inst/AP/2013/RR-16	Dr. M. Venkata Rama
5	Sri Gayatri super speciality hospital, kothavantenna center, achamamba street, Vijayawada - 520 002, Andhra Pradesh	Institutional Ethics Committee, SGSH, Sri Gayatri super speciality hospital, kothavantenna center, achamamba street, Vijayawada -520 002, Andhra Pradesh EC Reg. No ECR/1279/Inst/AP/2019	Dr . Sitaramarao
6	Sahyadri Hospital, 33/34B, Makarand Bhave Path, Karve road, Pune 411004	Sahyadri Hospitals Ltd. Ethics Committee (SCRDC), 33/34B, Makarand Bhave Path, Karve road, Pune 411004 EC Reg. No. ECR/493/ Inst/MH/2013/RR-16	Dr. Milind M Patil
7	KPC Medical College and Hospital, 1st floor, Raja S.C Mullick Road, Jadavpur, Kolkata - 700032	Institutional Ethics Committee, KPC Medical College and Hospital, Jadavpur, Kolkata -700032 EC Reg. No. ECR/306/ Inst/WB/2013/RR-16	Dr. Debmalya Sanyal
8	Indira Gandhi Institute of Medical Sciences (IGMS),Sheikhpura, Patna Bihar- 800014	Institutional Ethics Committee, IGIMS ,Sheikhpura Indira Gandhi Institute Of Medical Sciences Sheikhpura Raja Bazar Patna Patna Bihar – 800014 EC reg no ECR/640/Inst/BR/2014/RR-20	Dr Ved Prakash
9	Shalby Hospital, Opp. Karnavati Club, Sarkheji Gandhinagar Highway, Ahmedabad Gujarat - 380015	Ethics Committe-Shalby Limited,Shalby Limited Ahmedabad,Opp. Karnavati Club, S.G. Highway Ahmedabad,Gujarat - 380015 India EC reg no: ECR/711/Inst/GJ/2015/RR-21	Dr Shruti Kunal