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/23/000081 Dated 29-Dec-2023

To,

M/s Regenix Biosciences Limited,
Jamal Sonu Terrace,42/1,Loganthan Nagar
1st street,100 feet road,Choolaimedu,Chennai,Tamilnadu-600094.

Subject: Application for grant of permission to conduct Phase III clinical trial 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 (Investigational drug) -Regenix Insulin 30/70 with Eli Lilly's bacteria based Human Insulin Basal Bolus (Reference drug) - Huminsulin 30/70 in Type I and Type II Diabetes patients" as per Study protocol Protocol No. CT22-008, Version 03 dated 26.05.2023– regarding

Ref.: Your Application No BIO/CT04/FF/2023/38054 dated 15-06-2023

Sir,

With reference to your Application No. BIO/CT04/FF/2023/38054 dated 15-06-2023, 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;

(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;

(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 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;

(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 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 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;

(XIV) 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;

(XV) 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;

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

(XVII) 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.

(XVIII) 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.

(XIX) 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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,
2.5.4.20=80c62f6a23e4ea1be8a239774cdeb03c276 9041015a06564fe67f54b765db1cb,
postalCode=600034, st=TAMIL NADU,
serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013,
cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.01.08 18:01:20 +05'30'

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File. No. BIO/CT/23/000081

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 Regenix Biosciences Limited,Jamal Sonu Terrace,42/1,Loganthan Nagar,1st street,100 feet road,Choolaimedu,Chennai,Tamilnadu-600094** 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 (Investigational drug) -Regenix Insulin 30/70 with Eli Lilly's bacteria based Human Insulin Basal Bolus (Reference drug) - Huminsulin 30/70 in Type I and Type II Diabetes patients" as per Study protocol Protocol No. CT22-008, Version 03 dated 26.05.2023 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: 29.12.2023

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c2769041015a06564fe67f54b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.01.08 18:01:58 +05'30'

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

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug</td><td>Biphasic Isophane Insulin Injection IP100IU/ml(30% soluble insulin/70% isophane insulin)</td></tr>
<tr><td>Therapeutic class</td><td>Antidiabetic</td></tr>
<tr><td>Dosage form:</td><td>Suspension for injection</td></tr>
<tr><td>Composition:</td><td>Biphasic Isophane Insulin Injection IP 100IU/ml,10ml vial
<table>
<tr><th>Name of Ingredient</th><th>Function</th><th>Quantity per ml</th></tr>
<tr><td>Human Insulin (rDNA origin) IP#</td><td>Active ingredient</td><td>100IU</td></tr>
<tr><td>Liquified phenol USP#</td><td>Preservative</td><td>0.730mg</td></tr>
<tr><td>Metacresol USP</td><td>Preservative</td><td>1.6 mg</td></tr>
<tr><td>Glycerine IP</td><td>Tonicity agent</td><td>16 mg</td></tr>
<tr><td>Protamine sulphate IP</td><td>Complexing agent</td><td>0.241mg</td></tr>
<tr><td>Dibasic sodium phosphate USP</td><td>Buffer</td><td>3.780mg</td></tr>
<tr><td>Zinc oxide IP</td><td>Stabilizer</td><td>0.011mg</td></tr>
<tr><td>Hydrochloric acid(10%)* IP</td><td>pH adjustment</td><td>q.s</td></tr>
<tr><td>Sodium hydroxide(10%)* IP</td><td>pH adjustment</td><td>q.s</td></tr>
<tr><td>Water for Injection IP</td><td>solvent</td><td>q.s to 1 ml</td></tr>
<tr><td colspan="3">0.0347 mg of Human insulin is equivalent to 1.00 IU of Human insulin.
#Human insulin and Liquefied phenol using 1% overages
*For pH adjustment ,use 10% sodium hydroxide and 10% hydrochloric acid
Protamine sulphate,zinc oxide and dibasic sodium phosphate quantities are based on actual working quantity.
q.s = Quantity Sufficient</td></tr>
</table></td></tr>
<tr><td>Indications:</td><td>Diabetes Type I and Type II</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	St Anns General and Cancer Hospital, Kazipet, Warangal, Telangana -506004.	St. Anns Institutional Ethics Committee,ST. ANNS HOSPITAL,24-7-7/3 Fathimanagar, Darga Road Kazipet Warangal	Dr Shravan Kumar Ankathi

		Urban Telangana - 506004 India EC Reg. No. ECR/1297/Inst/TG/2019	
2	Acharya Vinoba Bhave Rural Hospital, DMIHER, JNMC, Sawangi, Wardha, Maharashtra, India-442004	Institutional Ethics Committee of DMIHER,Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, Maharashtra - 442004 **EC reg no:** ECR/440/Inst/MH/2013/RR-19	Dr.Shilpa Bawankule
3	Goroshi clinic- super speciality Diabetes, Thyroid and Endocrine clinic, Forum builders, 1st floor, above belagavi diagnostics, near kohlapur circle, below lords hotel, belagavi, karnataka-590016	Lakeview Ethics Committee,Lakeview Heart and Super Speciality Hospital, CTS No 5653/17-20, Mahatma Phule Road, Near Goaves, Shastri Nagar, Belagavi, Karnataka - 590010 **EC reg no:** ECR/1586/Inst/KA/2021	Dr. Manjunath Goroshi
4	Pulse Multispeciality Hospital, Sr. No.51/7/B/1, 1st Floor,Vishwa arcade opp. Deccan pavillion hotel, Mumbai- Bangalore highway, Narhe,Pune-411041	Ethics Committee of Pulse Multispecialty Hospital Pulse Multispeciality Hospital, Survey No. 51/7/B/1, Viswa Arcade, Bombay Bangalore Highway, At Post Narhe, Pune, Maharashtra - 411041 **EC reg no:** ECR/1339/Inst/MH/2020	Dr.Aditya Bari
5	Vedant Multispeciality Hospital, GP-83, Opp. Rotary club, Sambhaji Nagar, MIDC, Chinchwad, pune-411019	IEC-Vedant Multispeciality Hospital Vedant Multispeciality Hospital, Plot No. GP 83, G Block MIDC, Sambhajinagar, Chinchwad, Pune, Maharashtra – 411019 EC reg no: ECR/1426/Inst/MH/2020	Dr.Abhishek Madhav Karmalkar
6	Ojas Multispeciality Hospital, Sr no 203/1, D.Y Patil college Road, Ravet, Pune-412101	Ojas Multispeciality Hospital Ethics Committee, Ojas Multispeciality Hospital , SR. No. 203/1, D.Y Patil College Road, Ravet, Pune, Maharashtra – 412101. EC reg no: ECR/1284/Inst/MH/2019	Dr. Niranjan Pathak
7	Janta hospital and Maternity Centre Near Water Head Tank, Amara-Akhari Bypass, chunar road, Varanasi, Uttar Pradesh-221011, India	Janta Hospital Ethics Committee,Janta Hospital and Maternity Center, Survey No. 374, Amara- Akhari ByPass, Chunar Road, Varanasi, Uttar Pradesh – 221011 EC reg no:	Dr. Amit Bhaskar

		ECR/839/Inst/UP/2016/RR-19	
8	Pranav Diabetes Center,57/1, Nanda complex, Annaian Reddy Layout, Dodda Banaswadi, Bengaluru, Karnataka- 560043	Pranav Diabetes Center Ethics Committee, Pranav Diabetes Center, 57/1, Nanda Complex, Rammurthy Nagar, Main Road, Banaswadi, Bangalore, Urban Karnataka - 560043 EC reg no: ECR/1217/Inst/KA/2019/RR-22	Dr.Prasad G.M
9	Citizen hospital, #14, Dispensary Rd, 2nd phase, Kalasipalya, Bengaluru, karnataka-56000	Citizen Hospital Inst. Ethics Committee, Citizen Wellness LLP, New 14, 2nd Main Road, Kalasipaly Extn., Bangalore, Urban Karnataka – 560002 EC reg no: ECR/1591/Inst/KA/2021	Dr. Ambanna Gowda
10	FS Endocrine and Diabetic Centre,17-1-197/T/2/A,Opp IOC petrol pump,Bintrif Nagar,Saidabad,Telengana-500059	FS Independent Ethics Committee,FS Endocrine And Diabetes Centre,17-1-197/T/2/A, BINTRIF Nagar Madannapet, Hyderabad Telangana - 500059 India EC reg no: ECR/369/Indt/TG/2022	Dr. Faraz Farishta

CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA