



File No. BIO/CT/23/000012

Dated 16-Oct-2023

To,

M/s Regenix Biosciences Limited,
Jamal Sonu Terrace,42/1,Loganthan Nagar
1st street,100 feet road,Choolaimedu,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, India, Human Insulin Short acting (Investigational drug) - Regenix Insulin R with the Eli Lilly's bacteria based Human Insulin Short acting (Reference drug) – Huminsulin R® in Diabetes mellitus (Type 1 and Type 2) patients" as per Study protocol CT23-001 Version 02 dated 31 May 2023– regarding

Ref.: Your Application No BIO/CT04/FF/2023/35910 dated 09-02-2023

Sir,

With reference to your Application No. BIO/CT04/FF/2023/35910 dated 09-02-2023, 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;

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, Loganathan Nagar, 1st street, 100 feet road, Choolaimedu, 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, India, Human Insulin Short acting (Investigational drug) - Regenix Insulin R with the Eli Lilly's bacteria based Human Insulin Short acting (Reference drug) – Humuinsulin R® in Diabetes mellitus (Type 1 and Type 2) patients" as per Study protocol CT23-001 Version 02 dated 31 May 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: 16.10.2023

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CONTROL ORGANIZATION, ou=RAJEEV
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postalCode=600034, st=TAMIL NADU,
serialNumber=60001067, cn=Rajeev Singh
Raghuvaran(India)
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Central Licensing Authority

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

Names of the new drug or investigational new drug	Insulin Injection IP 100 IU/mL		
Therapeutic class	Antidiabetic		
Dosage form:	Solution for injection		
Composition:	Insulin Injection IP 100IU/ml,10ml vial		
	Name of Ingredient	Function	Quantity per ml
	Human Insulin (rDNA origin) IP#	Active ingredient	3.47mg
	Metacresol USP	Preservative	2.5 mg
	Glycerine IP	Tonicity agent	16 mg
	Hydrochloric acid* IP	pH adjustment	q.s
	Sodium hydroxide** IP	pH adjustment	q.s
	Water for Injection IP	solvent	q.s to 1 ml
	0.0347 mg of Human insulin is equivalent to 1.00 IU of Human insulin. #Human insulin using 1% overages *For API Solubilisation and pH adjustment **For pH adjustment q.s = Quantity Sufficient ## Zinc is not added externally to the formulation,it is endogenous zinc.		
	Indications:	Diabetes Type I and Type II	

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 Urban Telangana - 506004 India <u>EC Reg. No.</u> ECR/1297/Inst/TG/2019	Dr Shravan Kumar Ankathi
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: ECR/839/Inst/UP/2016/RR-19	Dr. Amit Bhaskar
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, Kalasipalya Extn., Bangalore, Urban Karnataka – 560002 EC reg no: ECR/1591/Inst/KA/2021	Dr. Ambanna Gowda
10	Inpatient Block, 2nd floor, Department of General Medicine, Gandhi Hospital, Musheerabad, Secunderabad, Hyderabad, Telangana-50000	Institutional Ethics Committee, Gandhi Medical College and Gandhi Hospital, Musheerabad, Secunderabad, Telangana – 500003 EC reg no: ECR/180/Inst/AP/2013/RR-19	Dr. S. Ravindra kumar

