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/24/000038 Dated: 29-11-2024

To,

M/s. BioGenomics Limited,
First Floor, Kothari Compound,
Opposite Tikuji-ni-Wadi, Thane,
Maharashtra (india)- 400610.

Subject: Application for grant of permission to conduct Phase III clinical trial titled – " A Phase III, Multi-Center, Open-Label, Randomized, Parallel Group Study to compare Efficacy, Safety And Immunogenicity Of Biosimilar Recombinant Insulin Glargine (Manufactured By Biogenomics Limited) With Lantus® (Manufactured By Sanofi) in Diabetes Mellitus Patientsas per protocol number BGL-IG-CTP301-V1, version 01 dated 15.01.2024- regarding

Ref. No. Your Application No. BIO/CT04/FF/2024/42592 dated 26-03-2024.

Sir,

With reference to your application No. BIO/CT04/FF/2024/42592 dated 26-03-2024, 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.

(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 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) 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) 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.

(XVIII) Clinical study report should be submitted to this office after completion of the Clinical trial.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

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 BioGenomics Limited First Floor Kothari Compound Opposite Tikuji-ni-Wadi Bus Stop Manpada Thane 400610** to conduct Phase III clinical trial titled- " A Phase III, Multi-Center, Open-Label, Randomized, Parallel Group Study To Compare The Efficacy, Safety And Immunogenicity Of Biosimilar Recombinant Insulin Glargine (Manufactured By Biogenomics Limited) With Lantus® (Manufactured By Sanofi) in Diabetes Mellitus Patients." as per Protocol No. BGL-IG-CTP301-V1, version 01 dated 15.01.2024 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

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Date: 2024.11.29 17:23:04 +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:	Insulin Glargine Injection I.P. (r-DNA origin), 100 IU/ml (BGL-GLAR), (r-DNA origin)
Therapeutic class	Anti-diabetic
Dosage form:	Solution for subcutaneous injection
Composition:	Each vial contains:

Name of Ingredients	**Quantity (100 IU/1mL) in vial**
Insulin glargine (r DNA origin) I.P.	100 IU
Zinc Chloride I.P./ E.P.	30 µg
m-Cresol I.P./ E.P.	2.70 mg
Glycerol 85% I.P./ E.P.	20.0 mg
Hydrochloric acid I.P./ E.P.	q.s.
Sodium Hydroxide I.P./ E.P	q.s
Water For Injection I.P./ E.P.	q.s. to 1.0 mL

Indication:	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.	SP Medical College and A G Hospitals,, Bikaner-334001, Rajasthan, India Bikaner Rajasthan - 334001	Ethics Committee, Ethics Committee, S P Medical College, Bikaner, Pawanpuri, Bikaner-334003, Rajasthan, India **ECReg.No.** ECR/27/SP/Inst/RJ/2013/RR-19	Dr Hardeva Ram Nehra
2.	Assured Care Plus Hospital, 4th and 5th floor, star Plus Complex, Lam Road, Near Mukhtidham Temple, NMC Divisional office Nashik Road, Nashik, Nashik Maharashtra - 422101	Institutional Ethics Committee, Assured Care Plus Hospital, 4th & 5th floor, Star Plus Complex, Lam Road, Near Muktidham Temple, NMC Divisional office, Nashik Road, Nasik, Maharashtra-422101, India **EC Reg. No.** ECR/1756/Inst/MH/2022	Dr Atulram Agrawal
3.	Banu Hospital-A Unit of PCRI Hospital Pvt.Ltd.,, 1-53, 1st linesrinagar, Nellore, Andhra Pradesh-542137 Srinagar Andhra Pradesh - 542137	PCRI Ethics Committee, PCRI Pvt. Hospitals, 1-53, 1st line srinagar, Nellore, Andhra Pradesh-542137 **EC Reg. No.** ECR/1851/Inst/AP/2023	Dr Mamidala Venkata Rama Mohan

4.	Apollo Excelcare Hospital, Paschim Boragaon, near Ganesh Mandir, NH37, Kamrup, Guwahati, Assam-781033, India Guwahati Assam - 781033	Institutional Ethics Committee, Excelcare Hospital, Paschim Boragaon, near Ganesh Mandir, NH37, Kamrup, Guwahati, Assam-781033, India **EC Reg. No.** ECR/1230/Inst/AS/2019/RR-22	Dr Manash Pratim Baruah
5.	Shree Giriraj Multispeciality Hospital, Unit of Shree Giriraj Lifecare Pvt. Ltd., 150 Feet, ring road, 27, Navjyot Park Main Road Rajkot Gujarat - 360005	Shree Giriraj Hospital Research Ethics Committee, Shree Giriraj Multispeciality Hospital, A Unit of Shree Giriraj Lifecare Pvt. Ltd., 150 Feet, ring road, 27, Navjyot Park Main Road, Rajkot-360005, Gujrat, India **EC Reg. No.** ECR/74/Inst/GJ/2013/RR-19	Dr Mayank Rameshchandra Thakker
6.	ESIC Model Hospital,, Bapunagar, Near Hardasnagar Police Chowki, Bapunagar, Bapunagar Gujarat - 380024	Shrey Hospital Institutional Ethics Committee, 270/B/5 near AMCO Bank, Stadium Circle, Navrangpura, Ahmedabad-380009, Gujrat, India **EC Reg. No.** ECR/1302/Inst/GJ/2019	Dr Mitali Desai
7.	Rajiv Gandhi Medical College and Chatrapati Shivaji Maharaj Hospital CSMH, Old Thane Belapur Road, Kalwa, Thane Maharashtra - 400605	Institutional Clinical Ethics committee, Rajiv Gandhi Medical College, and Chatrapati Shivaji Maharaj Hospital (CSMH), Old Thane Belapur Road, Kalwa, Thane 400605 **EC Reg. No.** ECR/469/Inst/MH/2013/RR-20	Dr Prasita Pravin Kshirsagar
8.	Osmania Medical College and Osmania General Hospital, Room No.306, Department ofEndocrinology, 20d Floor, Golden Jubilee Block, Afzal gunj, Hyderabad Telangana -500012	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095 **EC Reg. No.** ECR/300/Inst/AP/2013 RR-19	Dr K Neelavani
9.	Apex Hospitals Private Limited,, S P 4 and 6, Malviya Industrial Area, Malviya Nagar, Jaipur Rajasthan -302017	Institutional Ethics Committee Apex Hospitals Pvt Ltd, S P 4&6, Malviya Industrial Area, Malviya Nagar, Jaipur, Rajasthan-302017 **EC Reg. No.** ECR/380/Inst/RJ/2013/RR-19	Dr Vipul Khandelwal
10.	JLN Medical College, Kala Bagh, Ajmer Ajmer Rajasthan - 305001	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India **EC Reg. No.** ECR/1156/Inst/RJ/2018/RR-22	Dr Sanjiv Maheshwari

11.	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur Rajasthan - 302039	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur, Rajasthan-302039, India **EC Reg. No.** ECR/1222/Inst/RJ/2019/RR-22	Dr Prabhat Kumar Sharma