



File No. BIO/CT/19/000109

Dated 18-01-2024

To,

M/s BioGenomics Limited,
First Floor Kothari Compound
Opposite Tikuji ni Wadi Bus Stop Manpada Thane 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 Recombinant Insulin Aspart Mix30(Manufactured by BioGenomics Limited) with NovoMix®30(Manufactured by NovoNordisk),in Diabetes Mellitus Patients " as per protocol number BGL-IAM-CTP301-V2,version V2 dated 19.04.2023– regarding

Ref.: Your Application No BIO/CT04/FF/2019/17660 dated 27-12-2019

Sir,

With reference to your Application No. BIO/CT04/FF/2019/17660 dated 27-12-2019, 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;

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

Names of the new drug or investigational new drug	Insulin Aspart Mix 30 Solution for Injection/3 mL (100 U/ mL) USP Type I Glass Cartridge pre-fitted in pen		
Therapeutic class	Antidiabetic		
Dosage form:	Solution for injection		
Composition:	Name of Ingredient	Function	Quantity per ml
	Insulin aspart (rDNA origin) IP	Active ingredient	100IU
	Phenol IP/EP	Preservative	1.5mg
	m-cresol IP/EP	Preservative	1.72 mg
	Glycerol EP	Tonicity agent	16 mg
	Sodium Chloride EP/IP	Tonicity agent	0.87mg
	Disodium hydrogen phosphate dihydrate EP	Buffering agent	1.25 mg
	Protamine sulphate IP/EP	Protracting agent	0.32mg
	Zinc 2+(as ZnCl ₂)	Stabilizer	19.6µg
	Hydrochloric acid(10% w/w) IP/EP	pH adjustment	q.s
	Sodium hydroxide(10% w/w) IP/EP	pH adjustment	q.s
	Water for Injection	solvent	q.s to 1 ml
	Indications:	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	Asian Institute of Medical Sciences, P/72, Milap Nagar, MIDC, Dombivli (E) - 421203	Suraksha Ethics Committee Asian Institute of Medical Sciences, P/72, Milap Nagar, MIDC, Dombivli (E) – 421203 <u>EC Reg. No.</u> ECR/644/Inst/MH/2014/RR-20	Dr. Kadian Sandeep Kumar

2	Health Care Hospital 16/2/219, Pogathota, Nellore,Andhra Pradesh - 524001, India	VIJAYA ETHICS COMMITTEE – Vijaya Super Speciality Hospital,16 -II/41 Raghava Cine Complex Road, Pogathota, Nellore,Andhra Pradesh - 524001, India EC reg no: ECR/453/Inst/AP/2013/RR-19	Dr Mamidala Venkata Rama Mohan
3	Arthur Asirvatham Hospital, 42-A Kuruvikkaran Salai, Anna Bus Stand Near, Madurai-625020 Tamil Nadu,India	Institutional Ethics Committee, Arthur Asirvatham Hospital, 42-A Kuruvikkaran Salai,Anna Bus Stand Near, Madurai -625020 Tamil Nadu,India EC reg no: ECR/186/INST/TN/2013/RR-19	Dr.Arthur Joseph Asirvatham
4	Dr. Jivraj Mehta Smarak Health Foundation Bakeri Medical Research Center Ayojannagar, Near Shreyas Crossing Road, Jivraj Mehta Marg, Jivraj Park Ahmedabad - 380007,Gujarat,India	Dr. Jivraj Mehta Smarak Health Foundation Bakeri Medical Research Center Institutional EC Ayojannagar, Near Shreyas Crossing Road, Jivraj Mehta Marg, Jivraj Park Ahmedabad - 380007,Gujarat,India EC reg no: ECR/274/Inst/GJ/2013/RR-19	Dr Banshi Saboo
5	JLN Medical College Kala Bagh Ajmer- 305001,Rajasthan,India	Institutional Ethics Committee, Jawahar Lal Nehru Medical College,KalaBagh,Ajmer- 305001,Rajasthan EC reg no: ECR/1156/Inst/RJ/2018/RR-22	Dr.Sanjiv Maheshwari
6	Institutional Ethics Committee, NRS Medical College, Academic Building,1 St Floor, Office Of The Principal,138, AJC Bose Road, Kolkata- 700014, West Bengal, India.	Institutional Ethics Committee, NRS Medical College, Academic Building,1 St Floor, Office Of The Principal,138, AJC Bose Road, Kolkata- 700014, West Bengal, India EC reg no: ECR/609/Inst/WB/2014/RR-20	Dr. Badal Kumar Sahu
7	Osmania General Hospital, Endocrinology, Department of Endocrinology Room No 311, 2nd Floor, OP Building, Osmania General Hospital ,Osmania Medical College, Afzalgunj,Hyderabad- 500012, Telangana, India	Institutional Ethics Committee ,Osmania Medical College, Koti, Hyderabad – 500 095, Telangana, India EC reg no: ECR/300/Inst/AP/2013/RR-19	Dr. K.Neelaveni
8	Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Old Thane- Belapur Road, Budhaji Nagar, Kalwa West,Thane-	Institutional Clinical Ethics Committee; Dean Conference Room, First Floor, Rajiv Gandhi Medical College, and Chhatrapati Shivaji Maharaj	Dr.Prastia Kshirsagar

	400605	Hospital, Old Thane-Belapur Road, Budhaji Nagar, Kalwa West,Thane-400605 EC Reg no: ECR/469/Inst/MH/2013/RR-20	
9	Apex Hospitals Pvt. Ltd S P 4 & 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	Maharajav Agrasen Superspecialty Hospital Central Spine, Agrasen Aspatal Marg, Sector -7 Vidyadhar Nagar, Jaipur, Rajasthan - 302039	IEC Maharaja Agrasen Hospital Maharaja Agrasen Superspecialty Hospital Central Spine, Agrasen Aspatal Marg, Sector -7 Vidyadhar Nagar, Jaipur, Rajasthan – 302039 EC reg no: ECR/1222/Inst/RJ/20 19/RR-22	Dr. Prabhat Kumar Sharma

