File No. CT/13/23-DCG(I)

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

सत्यमेव जयते

File No. CT/23/000013

To,

M/s GCT Pharma Research (India) Pvt. Ltd.,
7th Floor, Wing-B, Vatika Business Centre, Hiranandani,
Gardens, Powai, Mumbai, Maharashtra (India) – 400076.

Sir,

With reference to your application No. GCT/CT04/FF/2023/35992 (GCT/13/23) dated 09-02-2023, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A randomized, international, multicenter single-blind study to compare the efficacy and safety of PZN-128 powder for solution for subcutaneous injection 250 µg (Pharmasyntez-Nord JSC, Russia) versus comparator drug in patients with chronic idiopathic (immune) thrombocytopenic purpura", Protocol No.: PZN-128, Protocol Version 2.0 - Ind dated 04/05/2023 with a total of up-to 70 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing 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 Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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) 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;

(xv) 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;

(xvi) the Central Licencing 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;

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

(xviii) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational 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.

Yours faithfully,

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=80c62f6a23e4eaf0e8a239774cdeb03c27 69041015a06564fe67f54b765db1cb,
postalCode=600034, st=TAMIL NADU,
serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013,
cn=RAJEEV SINGH RAGHUVANSHI
Date: 2023.07.25 11:54:00 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

File No. CT/13/23-DCG(I)

FORM CT-06

(See rules 22,25,26,29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

1. The Central Licensing Authority hereby **M/s GCT Pharma Research (India) Pvt. Ltd, 7th Floor, Vatika Business Centre, Supreme Business Park, Hiranandani Garden, Powai Powai (India) - 400076 Telephone No.: 22-42369729 FAX: 22-42019191 Email: U.SAHOO@GCTRIALS.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: PZN-128, Protocol Version 2.0-Ind dated 04/05/2023** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational 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 ________________

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=80c62f6a23e4eafbe8a239774cde b03c27690410 15a06564fe67f54b765db1c b, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03B DC902D0E1FE73CFA12A1A126EA94FA570 1124A19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2023.07.25 11:54:13 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	PZN-128
Therapeutic class:	Thrombopoietin agonist
Dosage form:	Vials
Composition:	Relative potency 64.0000 to156.0000 % In House Specification Active Size Exclusion (SE) HPLC >90.0000 % In House Specification Active Cation Exchange Chromatography (CEX) >70.0000 % In House Specification Active
Indications:	Chronic idiopathic (immune) thrombocytopenic purpura

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Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Rudraksha Multispeciality Hospital, 1st Floor, Rajmandir Complex, Off to Bareja fly over, Bareja-382425, Ahmedabad, Gujarat, India	Rudraksha Hospital Ethics Committee, Rudraksha Hospital, 1st Floor, Rajmandir Complex, Off to Bareja fly Over, Rudraksha Hospital Road, Bareja, Ahmedabad-382425, Gujarat, India ECR/1139/Inst/GJ/2018/RR-21	Dr. Raiyani Ankit Dhirajlal
2.	Malla Reddy Narayana Multispeciality Hospital, Suraram X-Roads, Jeedimetla, Hyderabad-500055 Telangana	Malla Reddy Medical College for Women Institutional Ethics Committee, Suraram X Roads, Jeedimetla, Hyderabad-500055 Telangana ECR/981/Inst/AP/2017/RR-20	Dr. Leelabati Toppo
3.	AMRI Hospitals, Mukundapur, 230, Barakhola, Jadavpur, Kolkata, West Bengal-700099	AMRI Hospitals, Mukundapur Ethics Committee, 230, Barakhola, Jadavpur, Kolkata, West Bengal-700099 ECR/1595/Inst/WB/2021	Dr. Prantar Chakrabarti
4.	Sanjeevan Hospital, plot no.23, of Karve road, Erandawane, Pune -4	EC Sanjeevan Hospital, Sanjeevan Hospital- Plot no.23, off Karve road, Erandawane, Pune -4 ECR/54/Inst/Maha/2013/RR-19	Dr. Sweta Rupesh Lunkad
5.	Hemato Oncology Clinic Ahmedabad Pvt. Ltd., "Vedanta Institute of Medical Science, First Floor, Nr. Samved Hospital Stadium Commerce Road, Navrangpura, Ahmedabd-380009, Gujarat, India	Care Institute of Medical Sciences, Opposite Panchamrut Bunglows, Near Shukan Mall, Off Science City Road, Sola Ahmedabad-380060, Gujarat, India ECR/206/Inst/GJ/2013/RR-20	Dr. Shah Sanket Prashantbhai
6.	Haemato Oncology Care Centre (HOCC), Kedar New India Mill Compound, Jetalpur Rd, Behind Swadia Patel Hospital, Vadodara, Gujarat-390020	Parikh Institutional Ethics Committee, Parikh Multipspeciality Health care Pvt. Ltd., A 4 Bhagvati Park Society, Opposite Tube Company, Near Apollo Clinic, Old Padra Road, Vadodara	Dr. Seema Bhatwadekar

		ECR/1734/Inst/GJ/2022	
7.	Aakash Healthcare Private Limited, Hospital Plot, Road No. 201, Sector-3, Dwarka, New Delhi-110075, India	Aakash Healthcare Institutional Ethics Committee, Aakash Healthcare Private Limited, Hospital Plot, Road No. 201, Sector-3, Dwarka, New Delhi-110075, India ECR/1265/Inst/DL/2019	Dr. Parinita Kaur
8.	Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra, India	Institutional Ethics Committee Poona Medical Research Foundation, E-4 C to E-F, 4th Floor, Fifth Avenue Condominium Dhole Patil Road, Pune-411001, Maharashtra, India ECr/24/Inst/MH/2013/RR-22	Dr. Vijay Ramanan
9.	CARE Hospitals, Road No. 1 & 10, Banjara Hills, Hyderabad, Telangana-500034, India	Institutional Ethics Committee CARE Hospitals, 66th Floor, Room No. 628, CARE Hospitals, Road No. 1, Banjara Hills, Hyderabad, Telangana-500034, India ECR/94/Inst/AP/2013/RR-21	Dr. B Sainath
10.	CARE CHL-Hospitals [Unit of Convenient Hospitals Pvt. Ltd.,], Near LIG Square, A. B. Road, Indore, Madhya Pradesh, India-452008	Integrity Ethics Committee, CARE CHL-Hospitals [Unit of Convenient Hospitals Pvt. Ltd.,], Near LIG Square, A. B. Road, Indore, Madhya Pradesh, India-452008 ECR/505/Inst/MP/2014/RR-20	Dr. Vinay Bohara
11.	Department of Hematology, Nil Ratan Sircar Medical College and Hospital 138 AJC Bose Road, Kolkata - 700014 West Bengal, India	Institutional Ethics Committee, Nil Ratan Sircar Medical College and Hospital 138 AJC Bose Road, Kolkata - 700014 West Bengal, India ECR/609/Inst/WB/2014/RR-20	Dr. Tuphan Kanti Dolai
12.	Hematology and Oncology Clinic, Abhyankar Nagar Road, Balraj Marg Junction. Dhantoli. Naypur-440012. Maharashtra, India	Institutional Ethics Committee-Rughwani Child Health Care Center, Rughwani Child Care Centre and Hospital 22. Sindhu Nagar. Mohanlal Rughwani Marg. Jaripatka. Nagpur Maharashtra - 440014 India ECR/1444/Inst/MH/2020	Dr. Shriram Kane

13.	Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Higher Education & Research, JNMC, Sawangi Meghe, Wardha - 442002, Maharashtra, India.	Institutional Ethics Committee, Research House, Near Food Court, Datta Meghe Institute of Higher Education & Research, Sawangi (M), Wardha-442004, Maharashtra, India ECR/440/Inst/MH/2013/RR-19	Dr. Shilpa Bawankule
14.	Rajiv Gandhi Cancer Institute & Research Centre, Sector-5 Rohini, New Delhi-110085, India	Institutional Review Board, Rajiv Gandhi Cancer Institute & Research Centre, Sector-5 Rohini, New Delhi-110085, India ECR/10/Inst/DC/2013/RR-19	Dr. Narendra Agrawal
15.	Shalby Hospital, Surat, Near Navyug College, Rander-Road, Surat-395005	Ethics Committee Shalby limited, 8th Floor, Board Room , Shalby Hospital, Surat, Near Navyug College, Rander-Road, Adajan, Surat-395005 ECR/1213/Inst/GJ/2019/RR-22	Dr. Hasmukh Balar
16.	Sri lakshmi Multi Speciality Hospital, 301, 3rd Main Road, near Indane Gas, V B Layout, Old Extension, Krishnarajapura, Bengaluru, Karnataka-560036	Pranav Diabetes Centre Ethics Committee, Nanda Complex, Annaian Reddy, Layout, Ramamurthy nagar Main Road, 57/1, Dodda Banaswadi Rd, Bengaluru, Karnataka-560043 ECR/1217/Inst/KA/2019	Dr. Manjunath U
17.	Meera Hospital, Devi Bhavan, Beside Dr Archarya's Hospital, Near Zojhwala Petrol Pump Bail Bazar. Kalyan (W)-421301	Meera Institutional Ethics Committee, Devi Bhavan, Beside Dr.Archarya'sHospital, NearZojhwala Petrol Pump.Bail Bazar, Kalyan (W)-421301 ECR/1005/Inst/MH/2017/RR-21	Dr. Gautam Sitaramji Ganvir
18.	Bhaktivedanta Hospital and Research Institute, Srishti Complex, Bhakti Vedanta Swami Marg, Opp ISKON Temple, Mira Road (East), Thane-401107	Bhaktivedanta Hospital Ethics Committee, Bhaktivedanta HEC Office, 6th Floor, Bhaktivedanta Hospital and Research Institute, Srishti Complex, Bhakti Vedanta Swami Marg, Opp ISKON Temple, Mira Road (East), Thane-401107 ECR/396/Inst/MH/2013/RR-19	Dr. Shilpa Gupta

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19.	Citizen Hospital, #14, 2'd Main, Dispensary Road, Kalasipalya, Bangalore - 560002.	Citizen Hospital Institutional Ethics Committee, Citizen Wellness LLP, new 14, 2nd Main Road, Kalasipalya Extn. Bangalore –Urban, 560002 ECR/1591/nst/KA/2021	Dr. Ambanna Gowda

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