



File No. BIO/CT/24/000051

Dated 07-Feb-2025

To,

M/s Ablenio Sciences Pvt. Ltd.
97 BG, Scheme No 74C, Vijay Nagar, Indore
Madhya Pradesh (India) - 452010

Subject: Application for grant of permission to conduct Phase II clinical trial titled – “A Phase II, Open Label, Multi-Dose Study of NM5072 in Subjects with Paroxysmal Nocturnal Hemoglobinuria (PNH)” as per Protocol No.: NM5072-PNH-109, Version Number: 2.0 dated 21 Oct. 2024 - regarding

Ref.: Your Application No. BIO/CT04/FF/2024/43211 dated 06-05-2024

Sir,

With reference to your Application No.: BIO/CT04/FF/2024/43211 dated 06-05-2024, 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) The firm should submit Insurance Certificate to this office before initiation of the study as per Protocol No. NM5072-PNH-109, Version Number: 2.0 dated 21 Oct. 2024.
- (II) 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;
- (III) 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;
- (IV) 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;
- (V) 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;
- (VI) 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;
- (VII) 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;

- (VIII) 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;
- (IX) 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;
- (X) 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;
- (XI) 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;
- (XII) 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;
- (XIII) 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;
- (XIV) 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;
- (XV) The laboratory owned by any person or a company or any other legal entity and utilized 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 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;
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (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 Firm should submit the clinical study report after the completion of the study.

Yours faithfully,

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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F. No. BIO/CT/24/000051
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi 110 002
Dated: 07.02.2025

To,

M/s Ablenio Sciences Pvt. Ltd.,
97 BG, Scheme No 74C, Vijay Nagar, Indore
Madhya Pradesh (India) – 452010

Sir,

With reference to your application Ref No. BIO/FormCT16/TL/2024/145615 dated 01.05.2024, please find enclosed herewith the license to import investigational new drug for conduct of clinical trial, bearing No. **TL/BIO/25/000003** under the provision of Drugs and Cosmetic Act and Rules to import the drug/drugs mentioned therein.

Kindly acknowledge receipt of this letter and its enclosures.

Yours faithfully,

RAJEEV SINGH

RAGHUVANSHI

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

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Date: 2025.02.07 14:58:00 +0530

Copy together with a copy of Import License No. **TL/BIO/25/000003**

Forwarded for information to:-

All port offices of CDSCO

FORM CT-17

(See rules 68, 69, 70, 71 and 72)

LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

Licence Number: **TL/BIO/25/000003**

The Central Licencing Authority hereby grants licence to M/s Ablenio Sciences Pvt. Ltd., 97 BG, Scheme No 74C, Vijay Nagar, Indore Madhya Pradesh (India) – 452010 to import following investigational new drug from **USA** for conduct of clinical trial as per Protocol No.: NM5072-PNH-109, Version Number: 2.0 dated 21 Oct. 2024 in the below mentioned clinical trial sites. [As per Annexure]

S. No.	Name of the new drug or investigational new drugs to be imported	Therapeutic class of new drug or investigational new drugs	Quantity to be imported*
1	NM5072, Solution for infusion in vial 20 mg/ml	Monoclonal Antibody	417 vials (10mL per vial)

*Supplier: M/s 3500 Patterson Drive, Bloomington, Indiana - 47402 United States.

- This license is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
- This license shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
- Details of overseas manufacturer and manufacturing site under this license.

S. No.	Name and address of manufacturer	Name and address of manufacturing site
01.	<ul style="list-style-type: none">M/s Catalent, 3500 Patterson Drive, Indiana (United States) - 47402-0970 Telephone No.: 8123556746 FAX: 8123556746	<ul style="list-style-type: none">M/s Catalent, 3500 Patterson Drive, Indiana (United States) - 47402 Telephone No.: 8123556746 FAX: 8123556746

- The licensee shall maintain the record of imported new drug or investigational new drugs.

Place: New Delhi
Date: 07.02.2025

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

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Annexure:

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	All India Institute of Medical Sciences (AIIMS) Room No. 202, 2 nd Floor, New Private Ward, Department of Hematology, Ansari Nagar East, New Delhi –110029	Institute Ethics Committee All India Institute of Medical Sciences Room no.102, 1 st floor, Old OT Block, Ansari Nagar, New Delhi –110029 EC Reg. No.: ECR/538/Inst/DL/2014/RR-20	Dr. Tulika Seth



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 Ablenio Sciences Pvt. Ltd., 97 BG, Scheme No 74C, Vijay Nagar, Indore Madhya Pradesh (India) – 452010 to conduct clinical trial of the new drug or investigational new drug study titled “A Phase II, Open Label, Multi-Dose Study of NM5072 in Subjects with Paroxysmal Nocturnal Hemoglobinuria (PNH)” as per Protocol No.: NM5072-PNH-109, Version Number: 2.0 dated 21 Oct 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.

Place: New Delhi

Date: 07-Feb-2025

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
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CDSCO

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

सत्यमेव जयते

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

Names of the new drug or investigational new drug:	NM5072 (Recombinant humanized monoclonal antibody)		
Therapeutic class:	Monoclonal Antibody		
Dosage form:	Solution for infusion in vial		
Composition:	Each vial contains: -		
	Ingredient	Function	Qty/Vial
	NM5072	Active ingredient	180.0 mg
	Histidine USP-NF, EP	Buffering agent	34.92 mg
	Sodium Chloride USP-NF, EP	Tonicity	57.86 mg
	Sucrose USP-NF, EP	Stabilizer	180 mg
	Polysorbate 80 USP-NF, EP	Surfactant, Stabilizer	0.90 mg
	Water for Injection USP-NF, EP	Solvent	Q.S.
Indications:	Paroxysmal Nocturnal Hemoglobinuria(PNH)		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	All India Institute of Medical Sciences (AIIMS) Room No. 202, 2 nd Floor, New Private Ward, Department of Hematology, Ansari Nagar East, New Delhi –110029	Institute Ethics Committee All India Institute of Medical Sciences Room no.102, 1 st floor, Old OT Block, Ansari Nagar, New Delhi –110029 EC Reg. No.: ECR/538/Inst/DL/2014/RR-20	Dr. Tulika Seth