

F. No. BIO/CT/24/000094
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi 110 002
Dated: 02.04.2025

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/2024/149971 dated 26.03.2025 received by this office through E-vartalaap, please find enclosed herewith the licence for “conduct of clinical trial” bearing No. **TL/BIO/25/000019** 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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2025.04.02 17:55:35 +05'30'

Copy together with a copy of Import License No. **TL/BIO/25/000019**

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/25/000019**

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 new drug from **USA** for conduct of clinical trial as per Protocol No.: NM8074-PNH-103, Version 3.0 dated 01 Aug 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	NM8074 (Monoclonal Antibody) 40 mg/ml Solution for infusion in vial	Monoclonal Antibody	987 vials (4.5 ml per vial)

*Supplier: M/s Fisher Clinical Services Inc. (Thermo Fisher Scientific), 699N. Wheeling Rd, Mt. Prospect, Illinois – 60056, Unites 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">Ajinomoto Althea Inc, 11040 Roselle Street, San Diego, California – 92121 (Unites States)Fisher Clinical Services (Fisher Clinical Services Inc., 699N. Wheeling Rd, Mt. Prospect, Illinois – 60056, Unites States.	<ul style="list-style-type: none">Ajinomoto Althea Inc, 11040 Roselle Street, San Diego, California – 92121 (Unites States)Fisher Clinical Services (Fisher Clinical Services Inc., 699N. Wheeling Rd, Mt. Prospect, Illinois – 60056, Unites States.

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

Place: New Delhi
Date: 02.04.2025

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

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, Room No 5017, 5 th Floor Teaching Block, Ansari Nagar, AIIMS, New Delhi - 110029	Institutional Ethics Committee, All India Institute of Medical Sciences, Old OT Block, Room No. 102, Ansari Nagar, AIIMS, New Delhi - 110029 <u>Registration No.</u> ECR/538/Inst/DL/2014/RR-20	Dr. Tulika Seth



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