



File No. BIO/CT/22/000111

Dated 17-Jul-2023

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 Study of NM8074 in Patients with Atypical Hemolytic Uremic Syndrome (aHUS)” as per Protocol No.: NM8074-aHUS-401, Version Number: 2.0 dated 27 April 2023 - regarding Ref.: Your Application No. BIO/CT04/FF/2022/34269 dated 13-10-2022

Sir,

With reference to your Application No.: BIO/CT04/FF/2022/34269 dated 13-10-2022, 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. NM8074-aHUS-401, Version Number: 2.0 dated 27 April 2023.
- (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.

Yours faithfully,

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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD
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RAGHUVANSHI,
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E1FE73CFA12A1A126EA94FA5701124A19013,
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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 Study of NM8074 in Patients with Atypical Hemolytic Uremic Syndrome (aHUS)” as per protocol No.: NM8074-aHUS-401, Version Number: 2.0 dated 27 April 2023, 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: 17-Jul-2023

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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: cn=RAJEEV SINGH RAGHUVANSHI, o=CENTRAL DRUGS STANDARD
CONTROL ORGANISATION, ou=DRUGS CONTROLLER GENERAL
RAJEEV SINGH RAGHUVANSHI, email=rajeev.singh.raghuvanshi@cdsco.gov.in,
c=IN, postalCode=110002, serialNumber=657F5E47D940985D8F038DC92,
dnQualifier=769041015a06564fe67f54b765db1cb,
serialNumber=657F5E47D940985D8F038DC92,
dnQualifier=DOE1FE73CFA12A1A126EA94FA5701124A19013,
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Annexure:**Details of new drug or investigational new drug:**

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|--|--|--------------------------|----------|
| Names of the new drug or investigational new drug: | NM8074 (Recombinant humanized monoclonal antibody) | | |
| Therapeutic class: | Humanized Complement Antibody | | |
| Dosage form: | Solution for infusion in vial | | |
| Composition: | Each vial contains: - | | |
| | Ingredient | Function | Qty/Vial |
| | NM8074 | Active | 180.0 mg |
| | Histidine USP-NF, EP | Buffering agent | 17.46 mg |
| | Sodium Chloride USP-NF, EP | Tonicity Adjusting Agent | 15.78 mg |
| | Sucrose USP-NF, EP | Cryoprotectant | 225 mg |
| | Polysorbate 80 USP-NF, EP | Surfactant | 0.45 mg |
| | Water for Injection USP-NF, EP, JP | Solvent | Q.S. |
| Indications: | Atypical Hemolytic Uremic Syndrome (aHUS) | | |

Details of clinical trial site:

| S. No. | Name and Address of Clinical Trial Site | Ethics Committee Details | Name of Principal Investigator |
|--------|--|---|--------------------------------|
| 1 | Sir Ganga Ram Hospital, Room No 1496. IV Floor, Old Building ,Old Rajinder Nagar New Delhi- 110060 | Sir Ganga Ram Hospital Ethics Committee Room No.- 1643 6 th Floor, Casualty Block Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi 110060. EC Reg. No.: ECR/20/Inst/DL/2013RR-19 | Dr. Vinant Bhargava |
| 2 | All India Institute of Medical Sciences, Department of Nephrology, Room no. 4094, 4th floor, Teaching Block, Ansari Nagar East, New Delhi – 110029 | Institute Ethics Committee All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital, Ansari Nagar, New Delhi - 110029 India EC Reg. No.: ECR/538/Inst/DL/2014/RR-20 | Dr. Raj Kanwar Yadav |