CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

761391Orig1s000

Trade Name:	Nemluvio for injection
Generic or Proper Name:	nemilizumab-ilto
Sponsor:	Galderma Laboratories, L.P.
Approval Date:	December 13, 2024
Indication:	For the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

CENTER FOR DRUG EVALUATION AND RESEARCH

761391Orig1s000

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Reviews / Information Included in this NDA Review.

Approval Letter	**X**
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Labeling	**X**
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Integrated Review(s)	**X**
Product Quality Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

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APPLICATION NUMBER:

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APPROVAL LETTER

BLA 761391/Original 1

BLA APPROVAL

Galderma Laboratories, L.P.
Attention: Joyel C. Morris
Director, Global Regulatory Strategy
2001 Ross Avenue, Suite 1600
Dallas, Texas 75201

Dear Joyel C. Morris:

Please refer to your biologics license application (BLA) dated and received December 13, 2023, under section 351(a) of the Public Health Service Act for Nemluvio (nemolizumab-ilto), injection.

BLA 761391 seeks licensure of Nemluvio (nemolizumab-ilto) 30 mg/0.49 mL pre-filled pen (b) (4)
For administrative purposes, we have split BLA 761391 into the following applications:

- BLA 761391/Original 1 – pre-filled pen, 30 mg/0.49 mL (b) (4)

The subject of this letter is for BLA 761391/Original 1 – pre-filled pen, 30 mg/0.49 mL. (b) (4) (b) (4)

(b) (4)

LICENSING

We have approved your BLA for Nemluvio (nemolizumab-ilto) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Nemluvio under your existing Department of Health and Human Services U.S. License No. 2289. Nemluvio is indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture nemolizumab-ilto drug substance at Chugai Pharma Manufacturing Co., Ltd., in Tokyo, Japan (FEI: 3004109596). The final formulated drug product dual chamber cartridge will be manufactured and filled at

[redacted] You may label your product with the proprietary name, Nemluvio, and market it in 30 mg of lyophilized powder for reconstitution and water for injection in a dual chamber cartridge for single-dose.

DATING PERIOD

The dating period for Nemluvio shall be 24 months from the date of manufacture when stored at 2 °C to 8 °C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be [redacted] months from the date of manufacture when stored [redacted] °C. We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Nemluvio to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of nemolizumab, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL AND LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

HIGHLIGHTS OF PRESCRIBING INFORMATION

- Update “Revised:” date to 12/2024.

FULL PRESCRIBING INFORMATION: CONTENTS*

- Capitalize the “D” in dosage for the heading, 2.2 Recommended Dosage for Atopic Dermatitis

FULL PRESCRIBING INFORMATION

- Update “©” year to 2024.

INSTRUCTIONS FOR USE

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

- Update the "Issued" date to 12/2024.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (Prescribing Information, Patient Package Insert, and Instructions for Use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761391/Original 1**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for nemolizumab was not referred to an FDA advisory committee because the application did not raise significant public health questions on the role of the biologic in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

We are waiving the pediatric study requirement for ages zero to less than 6 months of age because necessary studies are impossible or highly impracticable. This is because it is likely to be difficult to identify children <6 months who meet these eligibility criteria.

We are deferring submission of your pediatric studies for ages 6 months to less than 12 years for this application because adult studies are completed and ready for approval.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of this postmarketing studies must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

4721-1 Conduct a single-arm, open-label clinical trial to evaluate pharmacokinetics and safety in pediatric subjects from 2 years to less than 12 years of age with moderate-to-severe atopic dermatitis, which is not adequately controlled with topical therapy for a minimum duration of 52 weeks.

Final Protocol Submission: 11/2020
Study Completion: 04/2025
Final Report Submission: 10/2025

4721-2 Conduct a single-arm, open-label clinical trial to evaluate pharmacokinetics and safety in pediatric subjects from 6 months to less than 2 years of age with moderate-to-severe atopic dermatitis, which is not adequately controlled with topical therapy for a minimum duration of 52 weeks.

Final Protocol Submission: 07/2025
Study Completion: 11/2027
Final Report Submission: 05/2028

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 117122, with a cross-reference letter to this BLA. Reports of these required pediatric postmarketing studies must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED**

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

PEDIATRIC ASSESSMENTS" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4721-3 Conduct three shipping validation runs [redacted (b) (4)] to cover dual chamber cartridge (DCC) shipping [redacted (b) (4)] to the USA from a temperature control perspective. Provide the report and summary validation data.

The timetable you submitted on July 22, 2024, states that you will conduct this study according to the following schedule:

Final Report Submission: 10/2025

4721-4 Implement a test for additional sub-visible particles [redacted (b) (4)] µm in size in the drug product release and annual stability programs for dual chamber cartridge.

The timetable you submitted on August 6, 2024, states that you will conduct this study according to the following schedule:

Final Report Submission: 10/2025

Submit clinical protocols to your IND 117122 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[4]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80).

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, email H. F. Van Horn III, PharmD, MBA, Senior Regulatory Project Manager, at Howard.VanHornIII@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jill Lindstrom, MD, FAAD
Director
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JILL A LINDSTROM
12/13/2024 12:37:33 PM