U.S. FOOD & DRUG ADMINISTRATION

BLA 761390/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 12, 2023, submitted under section 351(a) of the Public Health Service Act for Nemluvio (nemolizumab-ilto) injection.

BLA 761390 seeks licensure of Nemluvio(nemolizumab-ilto) 30 mg/0.49 mL pre-filled pen (b) (4)
For administrative purposes, we have split BLA 761390 into the following applications:

- BLA 761390/Original 1 – pre-filled pen, 30 mg/0.49 mL (b) (4)

The subject of this letter is for BLA 761390/Original 1 – pre-filled pen, 30 mg/0.49 mL. (b) (4) (b) (4) (b) (4)

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2289 to Galderma Laboratories, L.P., Dallas, Texas, under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Nemluvio (nemolizumab-ilto). Nemluvio (nemolizumab-ilto) is indicated for adults with prurigo nodularis.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture nemolizumab-ilto drug substance at [redacted] 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 revisions listed below:

- Update all labeling with the issued license number

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.[1] Content of labeling must be identical to the enclosed labeling (text for the 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 (October 2009)*.[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 *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761390**." 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.

We are waiving the pediatric stud(ies) requirement for this application because necessary studies are impossible or highly impractical due to the low prevalence of this disease in pediatric population.

[1] See 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.

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

We remind you of your postmarketing commitments:

4682-1 Conduct three shipping validation runs [redacted] to cover dual chamber cartridge (DCC) shipping [redacted] 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: 10/25

4682-2 Conduct one shipping validation run in summer 2024 for final packaged autoinjector (AI) to validate the shipping from [redacted] to the US distribution sites 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: 10/24

4682-3 Implement a test for additional sub-visible particles [redacted] 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: 10/25

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**."

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

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*.[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 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 at 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:

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

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

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Kimberle Searcy, Regulatory Project Manager, at 240-402-4454 or kimberle.searcy@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Kathleen Donohue, MD
Acting Deputy Office Director
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/

KATHLEEN M DONOHUE
08/12/2024 04:52:16 PM