

BLA 761343/S-004

## **SUPPLEMENTAL BLA APPROVAL**

Alvotech USA Inc.  
PharmaLex US Corporation  
c/o Cencora  
Attention: Vandan Patel  
Sr. Specialist, Regulatory Affairs  
1 West 1st Avenue  
Conshohocken, PA 19428

Dear Vandan Patel:

Please refer to your supplemental biologics license application (sBLA) dated and received April 19, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Selarsdi (ustekinumab-aekn) injection.

We acknowledge receipt of your amendment dated March 11, 2025, which constituted a request for approval following our February 19, 2025, provisional determination letter.

This Category F Prior Approval supplemental biologics license application provides for:

- Selarsdi (ustekinumab-aekn) injection 45 mg/0.5 mL in a prefilled syringe (PFS) for subcutaneous use as interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL in a PFS for subcutaneous use.
- Selarsdi (ustekinumab-aekn) injection 90 mg/mL in a PFS for subcutaneous use as interchangeable with Stelara (ustekinumab) injection 90 mg/mL in a PFS for subcutaneous use.
- Selarsdi (ustekinumab-aekn) injection 45 mg/0.5 mL in a single-dose vial for subcutaneous use as interchangeable with Stelara (ustekinumab) injection 45 mg/0.5 mL in a single-dose vial for subcutaneous use.
- Selarsdi (ustekinumab-aekn) injection 130 mg/26 mL in a single-dose vial for intravenous use as interchangeable with Stelara (ustekinumab) injection 130 mg/26 mL in a single-dose vial for intravenous use.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **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,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

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*.

The SPL will be accessible via publicly available labeling repositories.

### **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.

At this time, no pediatric studies are required under PREA for this supplement.

### **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*.<sup>1</sup>

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 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.<sup>2</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>3</sup>

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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<sup>1</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>2</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>3</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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](http://FDA.gov).

If you have any questions, contact Chau Nguyen, Regulatory Project Manager at [chau.nguyen@fda.hhs.gov](mailto:chau.nguyen@fda.hhs.gov) or (240)-402-0022.

Sincerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH  
Deputy Director of Safety  
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
  - Medication Guide
  - Instructions for Use

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**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.**  
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/s/  
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TATIANA OUSSOVA  
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