BLA 761373/S-001
BLA 761425/S-001

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.
c/o Samsung Bioepis United States Inc.
Attention: Yelena Vaydman
Senior Manager, Regulatory Affairs
400 Frank W Burr Boulevard #125
Teaneck, NJ 07666

Dear Yelena Vaydman:

Please refer to your supplemental biologics license applications (sBLAs), dated and received July 29, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Pyzchiva (ustekinumab-ttwe) injection.

We acknowledge receipt of your major amendment dated October 15, 2024, which extended the goal date by two months.

The Prior Approval supplemental biologics license applications 761373/S-001 and 761425/S-001 provide for:

- Introduction of Pyzchiva (ustekinumab-ttwe) 45 mg/0.5mL injection in a single-dose autoinjector for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) 45 mg/0.5mL injection in a single-dose pre-filled syringe for subcutaneous use

- Introduction of Pyzchiva (ustekinumab-ttwe) 90 mg/mL injection in a single-dose autoinjector for subcutaneous use as biosimilar to and interchangeable with Stelara (ustekinumab) 90 mg/mL injection in a single-dose pre-filled syringe for subcutaneous use

- Addition of a new shipping system, (b) (4)

- Update of non-compendial incoming test item and acceptance criteria (b) (4)

- Change of raw material (b) (4)

BLA 761373/S-001 also provides for:

- Update of shipping qualification data based on [redacted] (b) (4) shipping qualification
- Update of Drug product (DP) stability protocol for the final long-term stability timepoint of 48-month to 42-month or 44-month
- Update of container closure integrity testing (CCIT) method description of DP stability

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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,[1] that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (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*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

[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 https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, 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 761373/S-001 and BLA 761425/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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 will be required under PREA for these sBLAs.

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

We remind you of your BLA 761373/S-001 postmarketing commitment (PMC):

4796-1 Conduct stability studies for one lot each of the ustekinumab-ttwe 45 mg autoinjector (AI) and ustekinumab-ttwe 90 mg AI presentations stored under long-term conditions. The AI shelf life supported by the stability study will reflect product age after assembly into the AI. Perform stability testing periodically through the end of shelf life following the pre-filled syringe (PFS) commercial long-term stability protocol in CTD Section 3.2.P.8.1 and using all tests in the PFS specifications in addition to the AI specifications. Provide the data in the PMC report at the completion of the studies.

The timetable you submitted on February 13, 2025, states that you will conduct this study according to the following schedule:

Final Report Submission: 01/29

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).

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

If you have any questions, contact Strother D. Dixon, Senior Regulatory Project Manager, at strother.dixon@fda.hhs.gov or (301) 796-1015.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - 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
06/27/2025 08:38:49 AM