BLA 761373/S-002
BLA 761425/S-002

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Samsung Bioepis Co., Ltd.
c/o ICON Clinical Research LLC
Attention: Wendy DeSpain, BSc, MBA, RAC
US Agent/Senior Director - US Regulatory Affairs
4130 Parklake Avenue, Suite 400
Raleigh, NC 27612

Dear Wendy DeSpain:

Please refer to your supplemental biologics license applications (sBLAs), dated and received August 20, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Pyzchiva (ustekinumab-ttwe) injection.

The Prior Approval supplemental biologics license applications 761373/S-002 and 761425/S-002 provide for:

- Introduction of Pyzchiva (ustekinumab-ttwe) injection 45 mg/0.5 ml vial for subcutaneous use as biosimilar to (b) (4) Stelara (ustekinumab) injection 45mg/0.5 mL vial for subcutaneous use;

- Response to post marketing requirement (PMR) 4572-1 titled, “Develop a presentation that can be used to accurately administer Pyzchiva to pediatric patients who weigh less than 60 kg.”

For administrative purposes, we have split sBLA 761373-002 into the following supplements:

- sBLA 761373-002 – biosimilarity
(b) (4)

The subjects of this correspondence are sBLA 761373-002 and sBLA 761425-002. (b) (4)
(b) (4)

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).

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-002 and BLA 761425/S-002**." Approval of this submission by FDA is not required before the labeling is used.

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[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.

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 note that you have fulfilled the pediatric assessment requirement for all relevant pediatric age groups for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated August 20, 2024, containing the final report for the following postmarketing requirement listed in the June 28, 2024, approval letter for BLA 761373 Original-1 and BLA 761425 Original-1.

4572-1 Develop a presentation that can be used to accurately administer Pyzchiva to pediatric patients who weigh less than 60 kg.

Final Report Submission: 12/2024

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing commitment listed in the June 28, 2024, approval letter that is still open.

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).

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}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
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/

TATIANA OUSSOVA
12/20/2024 04:20:55 PM