BLA 761262/S-005
BLA 761105/S-032

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

AbbVie Inc
Attention: Dan Pick
Associate Director, Global Regulatory Strategy
1 North Waukegan Road
Department PA72/Building AP30-4
North Chicago, IL 60064

Dear Dan Pick:

Please refer to your supplemental biologics license applications (sBLA), dated and received May 1, 2023 (BLA 761262/S-005), and December 19, 2023 (BLA 761105/S-032), and your amendments, submitted under section 351(a) of the Public Health Service Act for Skyrizi (risankizumab-rzaa) injection.

These Prior Approval supplemental biologics applications provide for changes to the Prescribing Information to add 0.9% Sodium Chloride as a diluent for preparation of the product for intravenous administration in section 2.7 *Preparation and Administration Instructions (Crohn's Disease)* and addition of information on the lack effect of risankizumab-rzaa on the metabolism of various CYPP450 substrates in subjects with Crohn's disease in section 12.3 *Pharmacokinetics* in response to a postmarketing commitment (PMC 4294-7).

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Updated the date of Recent Major Changes in Highlights of the Prescribing Information to reflect the approval date.
- Updated the revision date in Highlights and at the end of the Prescribing Information to reflect that approval date.

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).

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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

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

We remind you of your postmarketing commitment:

4556-1 Repeat the (b) (4) in-use compatibility study to confirm the stability of risankizumab drug product, aged at the end of shelf-life, upon preparation, storage, and administration using 5% dextrose in water as the diluent. The study results, including an analysis of subvisible particles, will be provided in the final report.

[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.

The timetable you submitted on November 22, 2023, states that you will conduct this study according to the following schedule:

Final Report Submission: 05/2024

Submit clinical protocols to your IND 118701 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**."

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submissions dated February 28, 2023, containing the final reports for the following postmarketing commitment listed in the June 16, 2022, approval letters for BLA 761105 and BLA 761262.

4294-7 Conduct a clinical trial to assess whether Skyrizi (risankizumab-rzaa) alters the metabolism or pharmacokinetics of cytochrome P450 (CYP) substrates in patients with Crohn's disease treated with Skyrizi (risankizumab-rzaa) (e.g., using a cocktail of relevant CYP probe drugs).

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

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]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication,

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

accompanied by a Form FDA 2253. 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

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, call me at (301) 796-9007 or email me at jay.fajiculay@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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.

/s/

JOYCE A KORVICK
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