BLA 125476/S-054
BLA 761133/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Takeda Pharmaceuticals, U.S.A., Inc.
Attention: Steffen Creaser PhD
Associate Director,
Global Regulatory Affairs Development, GI
40 Landsdowne Street
Cambridge, MA 02139

Dear Dr. Creaser:

Please refer to your supplemental biologics license applications (sBLAs), dated and received June 28, 2023, and February 20, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Entyvio (vedolizumab) for injection, Entyvio (vedolizumab) injection, and Entyvio Pen (vedolizumab) injection for subcutaneous use.

These Prior Approval supplemental biologics applications provide updates to the Entyvio Prescribing Information and Medication Guide based on results from the Entyvio pregnancy exposure registry, a prospective, observational cohort study conducted in collaboration with the Organization of Teratology Information Specialists (OTIS) and issued as a postmarketing commitment (PMC 2719-7).

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:

- Inserted the approval date in Highlights of the Prescribing Information and at the end of the Medication Guide
- Added a comma after “non-randomized design” in Section 8.1 Pregnancy, Data, Human Data

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 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).

FULFILLMENT OF POSTMARKETING COMMITMENT

This submission also contains the final report for the following postmarketing commitment listed in the May 20, 2014, approval letter for BLA 125476.

2719-7 Conduct a prospective, observational pregnancy exposure registry study in the United States that compares the pregnancy and fetal outcomes of women exposed to Entyvio (vedolizumab) during pregnancy to an unexposed control population or collect Entyvio (vedolizumab) pregnancy exposure data by collaborating with an existing disease-based pregnancy registry.

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

We remind you that there are postmarketing requirements and postmarketing commitments that are still open.

[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.

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 Kelly Richards, Senior Regulatory Health Project Manager, at (240) 402-4276 or email at kelly.richards@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology
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 (versions approved 9/28/2023)

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
02/23/2024 09:17:41 AM