BLA 761365/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Astellas Pharma US, Inc.
Attention: Sarah Groenendal
Director, Regulatory Affairs
2375 Waterview Drive
Northbrook, IL 60062

Dear Sarah Groenendal:

Please refer to your supplemental biologics license application (sBLA) received December 19, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for VYLOY (zolbetuximab-clzb), powder for injection.

This Prior Approval supplemental biologics application updates the VYLOY Prescribing Information (PI) Section 12.6 Immunogenicity to include new immunogenicity data that were provided in the final report supporting PMC 4723-2. In addition, it includes minor corrections to Sections 5 Warnings and Precautions, 6.1 Clinical Trials Experience, and Highlights of Prescribing Information.

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,[1] that is identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 none of these criteria apply to your supplement application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated December 19, 2024, containing the final report for the following postmarketing commitment listed in the October 18, 2024, approval letter for BLA 761365.

4723-2 Conduct an analysis of the incidence of anti-drug antibodies in clinical samples from pivotal clinical studies of zolbetuximab-clzb (i.e., SPOTLIGHT and GLOW) using a validated immunogenicity assay (e.g., 8951-ME-0006) and evaluate the potential clinical impact of the anti-drug antibodies on pharmacokinetics, efficacy, and safety of zolbetuximab-clzb.

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

[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.

We remind you that there are postmarketing commitments listed in the October 18, 2024, approval letter that are 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, call Nataliya Fesenko, Pharm.D., Senior Regulatory Health Project Manager, at (240) 402-6376.

Sincerely,

{See appended electronic signature page}

Steven Lemery, M.D., M.H.S.
Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

STEVEN J LEMERY
06/06/2025 01:44:57 PM