BLA 761208/S-010

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT
RELEASE FROM POSTMARKETING REQUIREMENT

Seagen Inc., a wholly owned subsidiary of Pfizer Inc
Attention: Melissa McMahon
Director, Global Regulatory Strategy for Oncology
10646 Science Center Drive
San Diego, CA 92121

Dear Melissa McMahon:

Please refer to your supplemental biologics license application (sBLA) received July 18, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for TIVDAK (tisotumab vedotin-tftv) injection.

This Prior Approval supplemental biologics application provides for updates to Section 8.4 (Pediatric Use) of the TIVDAK USPI based on the data submitted in the June 29, 2023, final report for PMR 4131-2 from the September 22, 2021, approval letter for BLA 761208.

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 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]

[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 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 the 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 REQUIREMENT

We have received your submission dated June 29, 2023, containing the final report for the following postmarketing requirement listed in the September 20, 2021, approval letter for BLA 761208.

4131-2 Conduct a pre-clinical study in pediatric-specific pre-clinical models with input from recognized key opinion leaders in pediatric oncology to support the conduct of clinical investigations of tisotumab vedotin in pediatric tumors.

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

RELEASE FROM POSTMARKETING REQUIREMENT

We have received your submission dated June 29, 2023, and July 18, 2025, related to the following postmarketing requirement listed in our September 20, 2021, approval letter:

4131-3 Conduct a clinical investigation of the dose, tolerability, and preliminary evidence of activity of tisotumab vedotin in pediatric patients with cancer(s) in which tissue factor is a relevant therapeutic target.

Draft Protocol Submission:	06/2024
Final Protocol Submission:	01/2025
Study Completion:	06/2029
Final Report Submission:	12/2029

We have reviewed your submissions and have determined that you are released from the above requirement as it is no longer needed due to the negative results from the pre-clinical study required under PMR 4131-2.

We remind you that there are postmarketing commitments listed in the September 20, 2021, 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, email Benjamin Chukwurah, Regulatory Project Manager, at benjamin.chukwurah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Christy Osgood, MD
Supervisory Associate Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

CHRISTY L OSGOOD
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