BLA 125388/S-104

SUPPLEMENT APPROVAL

Seagen Inc
Attention: John Brogan, Ph.D., RAC
Associate Director, Regulatory CMC
21823 30th Drive Se
Bothell, WA 98021

Dear Dr. Brogan:

Please refer to your Supplemental Biologics License Application (sBLA) dated February 24, 2023, received February 24, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Adcetris (brentuximab vedotin), for injection.

We also refer to our approval letter dated June 23, 2023, which contained the following errors:

- The postmarketing commitment (PMC) number was incorrectly listed as 4466-1. The correct PMC number is 4469-1.
- The statement "(b) (4)" was inadvertently included. This statement was removed.

This replacement approval letter incorporates the correction of the errors. The effective approval date will remain June 23, 2023, the date of the original approval letter.

This Prior Approval sBLA provides for (b) (4) changes made to the cAC10 antibody intermediate manufacturing process for brentuximab vedotin that were implemented as part of the 2020 campaign. These changes include, but are not limited to, (b) (4) (b) (4) the cAC10 antibody intermediate manufacturing process, which are collectively referred to as the "2020 Process Update." In addition, this Prior Approval supplemental biologics application provides for (b) (4) (b) (4) for the cAC10 antibody intermediate manufacturing process to ensure that (b) (4) in the cAC10 antibody intermediate.

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4469-1 Perform product-specific verification (e.g., matrix interference, limit of detection, and limit of quantitation with acceptable accuracy and precision) of the compendial (b) (4) method that will be used to control levels of (b) (4) (b) (4) (b) (4)

The timetable you submitted on June 16, 2023, states that you will conduct this study according to the following schedule:

Final Report Submission: May 1, 2024

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 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."**

This information will be included in your biologics license application file.

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Patrick Lynch

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