



BLA 125388/S-056  
BLA 125388/S-078

## SUPPLEMENT APPROVAL

Seattle Genetics, Inc.  
Attention: Elaine Waller, PharmD, MBA  
Senior Vice President, Regulatory Affairs  
21823 30<sup>th</sup> Drive, Southeast  
Bothell, WA 98021

Dear Dr. Waller:

Please refer to your Supplemental Biologics License Applications (sBLA), dated September 13, 2013, received September 16, 2013 (S-056) and October 23, 2014, received October 23, 2014 (S-078), submitted under section 351(a) of the Public Health Service Act for brentuximab vedotin (Adcetris<sup>®</sup>) Injection.

We acknowledge receipt of your amendments dated March 17, April 1, and September 3, 2014 (S-056) and November 21, 2014(S-078).

### Supplement S-056

This "Changes Being Effected" supplemental biologics application provides for the revisions to the Dosage and Administration section, Warnings and Precautions section, Adverse Reactions section, Post Marketing Experience section, Drug Interactions section and Patient Counseling Information section of the package insert.

### Supplement S-078

We also refer to our Safety Labeling Changes letter dated September 23, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for brentuximab vedotin (Adcetris<sup>®</sup>) Injection. This information pertains to the risk of hepatotoxicity.

This supplemental biologics application provides for revisions to the labeling for brentuximab vedotin (Adcetris<sup>®</sup>) Injection consistent with our September 23, 2014 letter.

## **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **WAIVER OF HIGHLIGHTS SECTION**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

## **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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert), and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 application, you are exempt from this requirement.

## **PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4) to the address above or by fax to 301-847-8444.

**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 Toni-Ann Cox, Regulatory Project Manager, at (240) 402 4775.

Sincerely,

*{See appended electronic signature page}*

Robert C. Kane, MD  
Deputy Director for Safety  
Division of Hematology Products  
Office of Hematology Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT C KANE  
11/23/2014