



BLA 125557/S-025

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Rajas Chodankar, Ph.D.
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop: 27-2-D
Thousand Oaks, CA 91320

Dear Dr. Chodankar:

Please refer to your supplemental biologics license application (sBLA), received November 7, 2022, submitted under section 351(a) of the Public Health Service Act for Blincyto (blinatumomab) injection.

This Prior Approval supplemental new drug application provides for release of the approved Blincyto (blinatumomab) risk evaluation and mitigation strategy (REMS). This supplement is in response to our October 25, 2022, REMS Modification Notification letter.

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Blincyto (blinatumomab) was originally approved on December 3, 2014, and the most recent REMS modification was approved on March 11, 2021. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Blincyto (blinatumomab) outweigh its risks because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goal. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Blincyto (blinatumomab).

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 application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.¹

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.² Information and Instructions for completing the form can be found at FDA.gov.³

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 Stacie Woods, Safety Regulatory Project Manager, at 301-796-4803, or via email at Stacie.woods@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shan M. Pradhan, M.D.
Associate Director for Safety (acting)
Office of Oncologic Diseases

¹ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

² <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

³ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

Center for Drug Evaluation and Research

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/

SHAN PRADHAN
12/05/2022 12:08:37 PM