

BLA 761324/S-010

## SUPPLEMENT APPROVAL

Genmab US, Inc.  
Attention: Kruti Patel, RPh  
Vice President, Regulatory Affairs  
777 Scudders Mill Road  
Bldg. 2, 4<sup>th</sup> Floor  
Plainsboro, NJ 08536

Dear Ms. Patel:

Please refer to your supplemental biologics license application (sBLA) received June 5, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Epkinly (epcoritamab-bysp) injection.

This Prior Approval sBLA provides for the updates to the product labeling to revise the recommendation for 24-hour hospitalization following administration of the first full 48 mg dose of epcoritamab on Cycle 1 Day 15 in patients with relapsed/refractory diffuse large-B cell lymphoma or high-grade B-cell lymphoma.

### **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,<sup>1</sup> 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*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

### **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 Natasha Kormanik, Senior Regulatory Project Manager, at (240) 402-4227 or [Natasha.Kormanik@fda.hhs.gov](mailto:Natasha.Kormanik@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Bindu Kanapuru, MD  
Deputy Director  
Division of Hematologic Malignancies II  
Office of Oncologic Diseases  
Office of New Drugs  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

- Content of Labeling
  - Prescribing Information
  - Medication Guide

**U.S. Food and Drug Administration**  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

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**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.**  
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/s/  
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