



BLA 761171/S-013

## SUPPLEMENT APPROVAL

Y-mAbs Therapeutics, Inc.  
Attention: Joshua Taylor, PhD, RAC  
U.S. Agent for Y-mabs Therapeutics  
202 Carnegie Center  
Suite 301  
Princeton, New Jersey 08540

Dear Dr. Taylor:

Please refer to your supplemental biologics license application (sBLA) received April 25, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for DANYELZA (naxitamab-gqgk) injection.

This “Changes Being Effected” supplemental biologics application provides for an update to the upper limit volume in DOSAGE AND ADMINISTRATION (2.4, *Preparation*) and to update the corporate address in the Prescribing Information, Patient Package Insert, and outer carton and vial labels.

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, Patient Package Insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to carton and container labeling submitted on April 25, 2025, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic*

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

*Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.* For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761171/S-13.**” Approval of this submission by FDA is not required before the labeling is used.

### **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.

### **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 Opeyemi Udoka, DPT, Senior Regulatory Project Manager, at 240-402-4558 or email [opeyemi.udoka@fda.hhs.gov](mailto:opeyemi.udoka@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Nicole Drezner, M.D.  
Deputy Director  
Division of Oncology 2  
Office of Oncologic Diseases  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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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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NICOLE L DREZNER  
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