BLA 761171/s-8

SUPPLEMENT APPROVAL

Y-mABs Therapeutics, Inc.
c/o Allucent
Attention: Lisa Sanders Ph.D., R.A.C.
U.S. Agent
2000 Centregreen Way, Suite 300
Cary, NC 27513

Dear Dr. Sanders:

Please refer to your supplemental biologics license application (sBLA), dated September 27, 2023, submitted under section 351(a) of the Public Health Service Act for Danyelza (naxitamab-gqgk) injection.

This Prior Approval supplemental biologics application provides for updates to the DOSAGE AND ADMINISTRATION (2.3, *Dosage Modifications for Adverse Reactions*), WARNINGS AND PRECAUTIONS (5.1, *Serious Infusion-Related Reactions*), (5.3, *Myocarditis*), (5.5, *Orthostatic Hypotension*), (5.6, *Embryo-Fetal Toxicity*), ADVERSE REACTIONS (6.3*, Postmarketing Experience/Spontaneous Reports*), USE IN SPECIFIC POPULATIONS (8.2, *Lactation*), (8.3, *Females and Males of Reproductive Potential*), and PATIENT COUNSELING INFORMATION sections of US Prescribing Information (USPI), in addition to revisions to the Patient Information to align with the USPI.

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,[1] that is identical to the enclosed labeling (text for the Prescribing Information,

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

and Patient Package Insert,) 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*.[2]

The SPL will be accessible via publicly available labeling repositories.

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).

[2] 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.

If you have any questions, call Opeyemi Udoka, D.P.T., Senior Regulatory Project Manager, at 240-402-4558 or email 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

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/

NICOLE L DREZNER
03/20/2024 03:48:38 PM