BLA 761210/S-02

**SUPPLEMENT APPROVAL/**
**FULFILLMENT OF POSTMARKETING**
**COMMITMENT**

Janssen Biotech, Inc.
Attention: Julie Brennan, MS, RAC
Director, Global Regulatory Affairs
920 U.S. Route 202
Raritan, NJ 08869

Dear Ms. Brennan:

Please refer to your supplemental biologics license application (sBLA), dated January 14, 2022, received January 14, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Rybrevant (amivantamab-vmjw) injection.

This Prior Approval sBLA provides for revisions to the Dosage and Administration (2.1 Patient Selection based on data related to PMC 4070-4) and Clinical Studies (14) sections of the U.S. Prescribing Information, clarifying data related to plasma testing.

## 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) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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

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 none of these criteria apply to your application, you are exempt from this requirement.

## FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated January 14, 2022, containing the final report for the following postmarketing commitment listed in the May 21, 2021, approval letter for BLA 761210.

4070-4 Submit a summary of the final report of an analytical and clinical validation study, using clinical trial data, that is adequate to support labeling of a tissue-based in vitro diagnostic device that demonstrates the device is essential to the safe and effective use of amivantamab-vmjw for patients diagnosed with NSCLC with EGFR exon 20 insertion mutations. The results of the validation study may inform product labeling.

We have reviewed your submission and conclude that the above commitment was fulfilled.

[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.

We remind you that there is a postmarketing requirement and postmarketing commitments listed in the May 21, 2021, approval letter that are still open.

## 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.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

## 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 Ashley Lane, Consumer Safety Officer, at Ashley.Lane@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Harpreet Singh, M.D.
Director
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

[3] For the most recent version of a guidance, check the FDA guidance web page athttps://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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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ERIN A LARKINS
11/04/2022 12:54:02 PM
As designated signatory authority for Dr. Harpreet Singh