U.S. FOOD & DRUG ADMINISTRATION

BLA 761163

BLA ACCELERATED APPROVAL

MorphoSys US Inc.
c/o Veristat, LLC
Attention: Mark Ammann, PharmD
President
134 Turnpike Road, Suite 200
Southborough, MA 01772

Dear Dr. Ammann:

Please refer to your biologics license application (BLA) dated December 28, 2019, received December 30, 2019, and your amendments, submitted under section 351 of the Public Health Service Act for Monjuvi (tafasitamab-cxix) for injection.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2152 to MorphoSys US Inc., Boston, MA, under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Monjuvi (tafasitamab-cxix). Monjuvi is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture tafasitamab-cxix drug substance and final formulated product at (b) (4) in (b) (4). The final formulated product will be labeled and packaged at (b) (4) (b) (4). You may label your product with the proprietary name Monjuvi and will market it in 200 mg for injection, lyophilized powder in a single-dose vial.

DATING PERIOD

The dating period for Monjuvi shall be 24 months from the date of manufacture when stored at 5 ± 3 °C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at (b) (4). We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Monjuvi and each kit component to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Monjuvi, or in the manufacturing facilities, will require the submission of information to your biologics license application for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL AND LABELING

We have completed our review of this application, as amended. It is approved under the provisions of accelerated approval regulations (21 CFR 601.41), effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations.

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] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert). 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.

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

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on May 29, 2020, 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 Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2018, Revision 5)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761163**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for tafasitamab-cxix was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues in the intended population.

ACCELERATED APPROVAL REQUIREMENTS

Products approved under the accelerated approval regulations, 21 CFR 601.41, require further adequate and well-controlled studies/clinical trials to verify and describe clinical benefit. You are required to conduct such clinical trials with due diligence. If postmarketing studies/clinical trials fail to verify clinical benefit or are not conducted with due diligence, we may, following a hearing in accordance with 21 CFR 601.43(b), withdraw this approval. We remind you of your postmarketing requirement specified in your submission dated July 29, 2020. This requirement, along with required completion dates, is listed below.

This postmarketing clinical trial is subject to the reporting requirements of 21 CFR 601.70:

3904-1 Submit the final report and datasets from a randomized, Phase 3 clinical trial to verify the clinical benefit of tafasitamab in patients with diffuse large B-cell lymphoma. The trial should include sufficient numbers of racial and ethnic minority patients to better reflect the U.S. patient population and allow for the interpretation of the results in these patient populations. Patients should be randomized to receive immunotherapy and/or chemotherapy with or without tafasitamab and lenalidomide. The primary endpoint should be progression-free survival, with secondary endpoints that include overall survival and objective response rate.

Draft Protocol Submission:	11/2020
Final Protocol Submission:	01/2021
Trial Completion:	06/2025
Final Report Submission:	12/2025

Submit clinical protocols to your IND 114856 for this product. In addition, under 21 CFR 601.70 you should include a status summary of each requirement in your annual report to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial.

Submit final reports to this BLA as a supplemental application. For administrative purposes, all submissions relating to this postmarketing requirement must be clearly designated "**Subpart E Postmarketing Requirement(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.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

3904-2 Submit an integrated final report containing data from clinical trials (including data from the ongoing clinical development program), post-marketing reports, compassionate use/expanded access program, real-world data and other sources to further characterize the safety and efficacy of tafasitamab in combination with lenalidomide among U.S. racial and ethnic minority patients with DLBCL.

The timetable you submitted on July 29, 2020, states that you will conduct this study according to the following schedule:

Preliminary Proposal Submission:	12/2020
Final Proposal Submission:	03/2021
Final Report Submission:	09/2026

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

3904-3 Re-evaluate the drug substance and drug product lot release and stability acceptance criteria for the ADCC assay after release data from 25 drug substance lots are available, and with consideration of available drug substance and drug product, release and stability data. The final report should include the corresponding data, the analysis thereof, and any proposed changes to the drug substance and drug product release or stability specifications resulting from the assessment.

The timetable you submitted on July 17, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 03/2024

3904-4 To provide results from at least one media fill run using (b) (4) vials to demonstrate successful (b) (4) with the vial size used for tafasitamab drug product. The final report should include the corresponding data from the media fill run and a summary of environmental monitoring.

The timetable you submitted on July 17, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 12/2020

3904-5 To perform shipment performance qualification using the first commercial batches of tafasitamab drug product. The shipment qualification results will be submitted in the annual report.

The timetable you submitted on July 17, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 08/2022

3904-6 To validate (b) (4) sample pre-treatment in combination with the (b) (4) assay to replace the current LAL endotoxin release test. The final validation report and any proposed changes to the description of the method will be submitted as a Changes Being Effected supplement.

The timetable you submitted on July 17, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 03/2021

3904-7 To demonstrate sensitivity of the Rabbit Pyrogen Test for endotoxin detection in the drug product using spiking studies. The final validation

report with the spiking study results will be submitted as a Changes Being Effected supplement.

The timetable you submitted on July 17, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 12/2020

Submit clinical protocols to your IND 114856 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

Under 21 CFR 601.45, you are required to submit, during the application pre-approval review period, all promotional materials, including promotional labeling and advertisements, that you intend to use in the first 120 days following marketing approval (i.e., your launch campaign). If you have not already met this requirement, you must immediately contact the Office of Prescription Drug Promotion (OPDP) at (301) 796-1200. Please ask to speak to a regulatory project manager or the appropriate reviewer to discuss this issue.

As further required by 21 CFR 601.45, submit all promotional materials that you intend to use after the 120 days following marketing approval (i.e., your post-launch materials) at least 30 days before the intended time of initial dissemination of labeling or initial publication of the advertisement. We ask that each submission include a detailed cover letter together with three copies each of the promotional materials, annotated references, and approved Prescribing Information, Medication Guide, and Patient Package Insert (as applicable).

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]

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

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80).

Prominently identify all adverse experience reports as described in 21 CFR 600.80. You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at FDA.gov.[4]

POST APPROVAL FEEDBACK MEETING

New molecular entities and new biologics qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas

[4] http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm

that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Jennifer Lee, Senior Regulatory Health Project Manager, at (240) 402-4622.

Sincerely,

{See appended electronic signature page}

Marc R. Theoret, MD
Deputy Director (Acting)
Office of Oncologic Diseases
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/

MARC R THEORET
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