

BLA 761097/S-008

## SUPPLEMENT APPROVAL

Regeneron Pharmaceuticals, Inc.  
Attention: Laura Simpson, Ph.D.  
Senior Director, Regulatory Affairs  
777 Old Saw Mill River Road  
Tarrytown, NY 10591

Dear Dr. Simpson:

Please refer to your supplemental biologics license application (sBLA), dated and received September 3, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Libtayo (cemiplimab-rwlc) injection.

We also refer to our January 21, 2021, electronic mail (email) communication, wherein we notified you that we planned to administratively split BLA 761097/S-008, with the proposed indication of "LIBTAYO is indicated for the treatment of patients with locally advanced or metastatic basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor," into the following two supplements:

- BLA 761097/S-008: LIBTAYO is indicated for the treatment of patients with locally advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor.
- BLA 76097/S-009: LIBTAYO is indicated for the treatment of patients with metastatic basal cell carcinoma previously treated with a hedgehog pathway inhibitor.

This Prior Approval supplemental biologics application provides for a new indication for cemiplimab-rwlc, for the treatment of patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

### **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.

## **WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## **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 Effectuated” (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.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (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.

We are waiving the pediatric study(ies) requirement for this application because necessary studies are impossible or highly impracticable.

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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>.

## **POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitment:

4011-1      Submit the final analysis of objective response rate and duration of response for the 84 patients with locally advanced basal cell carcinoma (laBCC) whose data was included in BLA supplement-008, in order to further characterize the durability of response in this cohort. For the analysis, all patients will have the opportunity for at least 1.5 years of follow-up following completion of cemiplimab-rwlc treatment. The study results may inform product labeling.

The timetable you submitted on January 26 and 29, 2021, states that you will conduct this study according to the following schedule:

Final Protocol Submission: 04/2021

Trial Completion:                    08/2023

Final Report Submission: 05/2024

Submit the datasets with the final report.

A final submitted protocol is one that the FDA has reviewed and commented upon, and you have revised as needed to meet the goal of the study or clinical trial.

Submit clinical protocols to your IND 127100 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**

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*.<sup>3</sup>

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

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.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

## **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 Leah Her, Senior Regulatory Health Project Manager, at (240) 402-6611 or [leah.her@fda.hhs.gov](mailto:leah.her@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Lola Fashoyin-Aje, M.D., M.P.H.  
Deputy Director  
Division of Oncology 3  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <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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