



BLA 761289/S-006

**CORRECTED SUPPLEMENT APPROVAL/
FULFILLMENT OF
POSTMARKETING REQUIREMENT**

AstraZeneca AB
c/o AstraZeneca Pharmaceuticals LP
Attention: Cecil Washington
Associate Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Dear Cecil Washington:

Please refer to your supplemental biologics license application (sBLA), dated January 26, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Imjudo (tremelimumab-actl) for intravenous infusion.

We also refer to our letter dated July 24, 2024. That letter contained the following error: incorrect labeling attached.

This corrected letter incorporates the correction of the error.

This Prior Approval supplemental biologics application updates the United States Prescribing Information (USPI) and structured product labeling (SPL) with the results from study D419EC00001, entitled, "A Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of tremelimumab in combination with durvalumab in pediatric patients." Changes are to the Pediatric Use subsection of the "USE IN SPECIFIC POPULATIONS" section of the labeling.

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 HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 Medication Guide) 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated December 8, 2023, containing the final report for the following postmarketing requirement listed in the September 5, 2023, post approval postmarketing requirement letter for BLA 761289.

- 4333-6 Conduct Study D419EC00001 (A Phase I/II, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of tremelimumab in combination with durvalumab in pediatric patients) to further characterize the safety, pharmacokinetics, and efficacy of tremelimumab in combination with durvalumab in patients from birth to <18 years of age with relapsed/refractory malignant solid tumors for whom no standard treatment is available. Include at least 12 patients in the dose escalation cohort and at least 21 patients in the dose expansion cohort.

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>.

Study Completion: 09/2023
Final Report Submission: 03/2024

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

We remind you that there are postmarketing commitments listed in the October 21, 2022, 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

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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).

³ For the most recent version of a guidance, check the FDA guidance web page at <https://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>

If you have any questions, contact Christina Leach, Senior Regulatory Health Project Manager, at Christina.Leach@fda.hhs.gov or 240-402-6571.

Sincerely,

{See appended electronic signature page}

Steven Lemery, M.D., M.H.S.
Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Medication Guide

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/

STEVEN J LEMERY
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