BLA 761069/S-12

SUPPLEMENT APPROVAL

AstraZeneca UK Ltd.
Attention: Ajay Parashar, PharmD, MS, MDD, RAC
Director, Global Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

Dear Dr. Parashar:

Please refer to your supplemental biologics license application, dated and received October 13,2016, and your amendments received September 25, 2018, March 15, 2019, August 9, 2019, September 27, 2019, February 21, 2020, April 10, 2020, June 23, 2020, July 31, 2020, September 4, 2020, October 19, 2020, and November 3, 2020, submitted under section 351(a) of the Public Health Service Act for Imfinzi (durvalumab) injection.

We also refer to our July 18, 2018, supplement request proposing changes to the approved labeling for the DOSAGE AND ADMINISTRATION, Dose Modifications subsection and the WARNINGS AND PRECAUTIONS, Immune-mediated Adverse Reactions subsections of the U.S. prescribing information.

We further reference our January 24, 2020, labeling discussion correspondence, which also included our purpose and goal to harmonize programmed death-ligand 1 (PD-L1) blocking antibodies and programmed cell death protein 1 (PD-1) blocking antibodies with respect to immune-mediated adverse reactions across all PDL1/PD1 antibody drug products.

This Prior Approval supplemental biologics application provides for revisions to the U.S. prescribing information and medication guide to improve the presentation of drug safety information regarding immune-mediated adverse reactions across all Food and Drug Administration (FDA) approved programmed death-ligand 1 and programmed cell death protein 1 blocking antibody labels. In addition, editorial and formatting changes were made throughout the U.S. package insert for consistency with current labeling practices.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Updated the date at the end of the Highlights of Prescribing Information and Medication Guide to “Revised: 11/2020”.

WAIVER OF 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, Patient Package Insert 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 Biologic License Application, 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).

[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.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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.

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]

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety 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 601.12(a)(4).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved Biologic License Application (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions you may contact Felicia Diggs, Safety Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

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[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

Sincerely,

{See appended electronic signature page}

Jefferey Summers, MD
Associate Director for Translational Sciences
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

JEFFERY L SUMMERS
11/10/2020 03:52:18 PM