BLA 761069/S-059

CORRECTED SUPPLEMENT APPROVAL

AstraZeneca UK Limited
c/o: Manny Khaira, PharmD, RPh
Regulatory Affairs Director (US Agent)
One MedImmune Way
Gaithersburg, MD 20878

Dear Dr. Khaira:

Please refer to your supplemental biologics license application (sBLA) received June 26, 2026, and your amendments, submitted under section 351(a) of the Public Health Service Act for Imfinzi (durvalumab) injection.

We also refer to our approval letter dated November 13, 2026, which contained the following error: the Applicant had inadvertently removed information related to BLA 761069/S-053 from the Medication Guide.

This corrected action letter incorporates the correction of the error. The effective action date will remain November 13, 2026, the date of the original letter.

This Prior Approval sBLA provides for the expansion of the indication to the following:

IMFINZI in combination with enfortumab vedotin-ejfv as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment after radical cystectomy, is indicated for the treatment of adult patients with MIBC who are ineligible for or who have refused cisplatin-based chemotherapy.

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

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

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 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 the 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 requirement for this application because necessary studies are impossible or highly impracticable on the basis that bladder cancer is an adult-related condition that rarely occurs in the pediatric population.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

5099-1 Complete the ongoing clinical trial VOLGA (D910PC00001; NCT04960709), titled "Durvalumab in combination with enfortumab vedotin as neoadjuvant treatment followed by durvalumab monotherapy as adjuvant treatment after radical cystectomy in patients with MIBC who are ineligible for or have refused cisplatin-based chemotherapy". Submit the pre-planned final overall survival analysis results to further characterize the clinical benefit of perioperative durvalumab in combination with neoadjuvant enfortumab vedotin for the treatment of

[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.

adult patients with MIBC who are ineligible for or who have refused cisplatin-based chemotherapy.

The timetable you submitted on November 9, 2026, states that you will conduct this study according to the following schedule:

Trial Completion:	06/2029
Final Report Submission:	12/2029

Submit the OS analyses and datasets with the final report submission.

Submit clinical protocols to your IND 125017 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/subjects 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 guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

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 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[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] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Christal Lee, Regulatory Project Manager, at Christal.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Daniel Suzman, MD
Deputy Director
Division of Oncology 1
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/

DANIEL L SUZMAN
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