



BLA 761049/S-019

**SUPPLEMENT APPROVAL  
FULFILLMENT OF POSTMARKETING COMMITMENT**

EMD Serono, Inc.  
Attention: Abidemi Alli, BSc, MBA  
Director Global Regulatory Affairs - Immuno-Oncology  
45A Middlesex Turnpike  
Billerica, MA 01821

Dear Abidemi Alli:

Please refer to your supplemental biologics license application (sBLA), dated and received May 13, 2024, submitted under section 351(a) of the Public Health Service Act for Bavencio (avelumab).

This Prior Approval Supplemental biologic license application provides the final analysis of overall survival from Study B9991003 (JAVELIN Renal 101).

**APPROVAL & LABELING**

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed 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,<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 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*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

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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>.

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.

Because these criteria do not apply to your supplement application, you are exempt from this requirement.

### **FULFILLMENT OF POSTMARKETING COMMITMENT**

We have received your submission dated May 13, 2024, reporting on the following postmarketing commitment listed in the May 14, 2019, approval letter for BLA 761049/S-006.

- 3588-2 Provide the final overall survival analysis, datasets, and labeling with the final report from clinical trial Javelin Renal 101 entitled; “A Phase 3, Multinational, Randomized, Open-Label, Parallel-Arm Study of Avelumab in Combination with Axitinib (INLYTA) versus Sunitinib (SUTENT) Monotherapy in the First-Line Treatment of Patients with Advanced Renal Cell Carcinoma.”

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

This completes all your postmarketing requirements and postmarketing commitments acknowledged in our May 14, 2019, letter. You are not required to report on the status of closed (released or fulfilled) postmarketing requirements and commitments in your annual report required under 21 CFR 314.81(b)(2)(vii) of the FD&CA.

### **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>

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.<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 Anna Lananh Nguyen, PharmD, Regulatory Project Manager, via email at [Lananh.Nguyen@fda.hhs.gov](mailto:Lananh.Nguyen@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

## ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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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>.

<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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DANIEL L SUZMAN  
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