BLA 125514/S-162

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.
Attention: Steven Mundt, M.S.
Director, Global Regulatory Affairs
126 East Lincoln Avenue
PO Box 2000, RY34-B293
Rahway, NJ 07065

Dear Steven Mundt:

Please refer to your supplemental biologics license application (sBLA), dated March 28, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Keytruda (pembrolizumab) Injection.

This Prior Approval sBLA provides the End-of-Trial report, datasets, and Final Report Submission to fulfill Postmarketing Commitment (PMC) 3876-1 and to update the KEYTRUDA (pembrolizumab) Prescribing Information Section 14.18 Cutaneous Squamous Cell Carcinoma section based on the final analysis of study KEYNOTE-629.

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)

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

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).

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 supplemental application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your March 28, 2024, submission containing the final report for the following postmarketing commitment listed in the June 24, 2020, approval letter for BLA 125514 /S-068.

3876-1 Submit the final report and datasets from Keynote-629 evaluating overall response rate and duration of response in patients with locally advanced cutaneous squamous cell carcinoma and those with recurrent or metastatic cutaneous squamous cell carcinoma, that may inform product labeling. All patients will have the opportunity for at least 1.5 years of follow-up following completion of pembrolizumab treatment to further characterize the durability of responses.

[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.

We have reviewed your submission and conclude that the above commitment was fulfilled. This completes all of your postmarketing commitments acknowledged in our June 24, 2020, letter. You are not required to report on the status of closed (released or fulfilled) PMC in your annual report required under 21 CFR 601.70 of the FD&CA.

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, call Haroon Vohra, Pharm.D., Senior Regulatory Project Manager, at 240-402-4471.

Sincerely,

{See appended electronic signature page}

Chana Weinstock, M.D.
Deputy Director (Acting)
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information

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/

CHANA WEINSTOCK
12/11/2024 09:51:43 AM