BLA 125514/S-106

SUPPLEMENT APPROVAL/ RELEASE FROM POSTMARKETING REQUIREMENT

Merck Sharp & Dohme Corp.
Attention: Robert Kester
Director, Global Regulatory Affairs
126 E. Lincoln Ave., P.O. Box 2000
RY34-B295
Rahway, NJ 07065

Dear Mr. Kester:

Please refer to your supplemental biologics license application (sBLA), dated and received March 3, 2021, submitted under section 351(a) of the Public Health Service Act for KEYTRUDA (pembrolizumab) injection, for intravenous use.

This Prior Approval supplemental biologics application provides for revisions to the full prescribing information and Medication Guide to voluntarily withdraw the indication for the treatment of patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy that was approved under title 21 of the Code of Federal Regulations (CFR) section 601 subpart E for accelerated approval of biological products for serious or life-threatening illness under BLA 125514/S-53 on June 17, 2019.

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 Food and Drug Administration (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).

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.

RELEASE FROM POSTMARKETING REQUIREMENT

We note that the following postmarketing requirement to verify clinical benefit was a condition of the accelerated approval as stated in our June 17, 2019, approval letter:

3599-1 Conduct and submit the results of at least one multicenter, randomized clinical trial establishing the superiority of pembrolizumab over available therapy as determined by an improvement in overall survival in patients with extensive stage small cell lung cancer.

[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.

We have determined that you are released from the above postmarketing requirement as it is no longer needed because the product indication of metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy is withdrawn from the label.

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, please email Sharon Sickafuse, Senior Regulatory Health Project Manager at sharon.sickafuse@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Harpreet Singh, M.D.
Director
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Package Insert
  - 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/

B HARPREET SINGH
03/30/2021 01:37:28 PM