BLA 125554/S-083

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
COMMITMENT

Bristol-Myers Squibb Company
Attention: Elvis Osei-Tutu, Pharm.D.
Associate Director - Global Regulatory Lead, Global Regulatory Strategy & Policy
P.O. Box 5326
Princeton, NJ 08543-5326

Dear Dr. Osei-Tutu:

Please refer to your supplemental biologics license application (sBLA), dated and received March 26, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Opdivo (nivolumab), injection, 100 mg/10 mL, 40 mg/4 mL and 240 mg/24 mL.

This Prior Approval supplemental biologics application provides for updates to the CLINICAL STUDIES, Small Cell Lung Cancer (14.4) subsection of the full prescribing information, Table 39, *Efficacy Results -Checkmate 032*, to include mature data from all 13 of the 109 responding patients who have been followed for a minimum of 24 months in order to accurately characterize the BIRC-assessed duration of response observed with nivolumab, as a single agent, for the third-line treatment of SCLC and additionally remove the 6 months duration of response data in the label..

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) 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.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated October 23, 2019, containing the final report for the following postmarketing commitment listed in the August 16, 2018 approval letter for BLA 125554/S-067.

3468-2 Submit the final report, including datasets, for CHECKMATE-032, in which all 13 of the 109 responding patients identified in the interim study report submitted to BLA 125554/ S-067, have been followed for a minimum of 24 months, to more accurately characterize the BIRC-assessed durability of

[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.

the response observed with nivolumab, as a single agent, for the third-line treatment of small cell lung cancer for inclusion in product labeling.

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

We remind you that there is a postmarketing requirement listed in the August 16, 2018 approval letter that is still open.

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 Kwadwo Korsah, Pharm.D., Regulatory Health Project Manager, at (301) 796-6630.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
- Content of Labeling

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
06/23/2020 11:03:01 AM