NDA 209936/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKING REQUIREMENT

Bayer HealthCare Pharmaceuticals Inc.
Attention: Anita K. Murthy, PharmD
Global Regulatory Leader, Oncology 3
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Dr. Murthy:

Please refer to your supplemental new drug application (sNDA) dated May 1, 2019, received May 1, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALIQOPA (copanlisib) for injection.

This Prior Approval supplemental new drug application provides for the following updates in the United States Prescribing Information (USPI): revised the order of subsections in Dosage and Administration, added dosing recommendations and pharmacokinetic (PK) data for patients with hepatic impairment, reformatted drug interaction information, and added information regarding QTc prolongation based on findings from study 16270.

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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.1 Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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 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 REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated February 5, 2019, containing the final report for the following postmarketing requirement listed in the September 14, 2017, approval.

PMR 3273-3 Complete and submit results of a study to determine the effect of Aliqopa on QT/QTc interval in subjects with advanced solid tumors and non-Hodgkin's lymphoma. The trial should be designed and conducted in accordance with the FDA Guidance for Industry entitled, "*E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs*."

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

[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 remind you that there are postmarketing requirements listed in the September 14, 2017, approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rosa Lee-Alonzo, Senior Regulatory Health Project Manager, at (301) 348-3004.

Sincerely,

{See appended electronic signature page}

Albert Deisseroth, MD, PhD
Supervisory Associate Division Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

ALBERT B DEISSEROTH
10/28/2019 04:19:14 PM