NDA 211651/S-002

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Pfizer, Inc.
Attention: Katarzyna Kowanetz, PhD, RAC
Senior Manager, Worldwide Safety and Regulatory
525 Market Street, 36th Floor
San Francisco, CA 94105

Dear Dr. Kowanetz:

Please refer to your supplemental new drug application (sNDA) dated February 27, 2019, received February 27, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Talzenna™ (talazoparib) capsule; 0.25 mg and 1 mg.

This Prior Approval supplemental new drug application provides for revisions to the Drug Interactions and Clinical Pharmacology sections of the Full Prescribing Information based on the final report and datasets from C3441004 study.

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 and Patient Package Insert), 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(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 February 27, 2019, containing the final report(s) for the following postmarketing commitment listed in the October 16, 2018 approval letter.

3476-4 Submit the final report and data sets from the clinical trial (Protocol C3441004) entitled, “A Phase 1, Open-Label, Two-Arm, Drug-Drug Interaction Study to Evaluate the Effect of Rifampin on the Pharmacokinetics of Talazoparib in Patients with Advanced Solid Tumors” to determine appropriate dosing recommendations when coadministering talazoparib with P-gp inducers

We have reviewed your submission and conclude that the above commitment 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 requirement(s) and postmarketing commitment(s) listed in the October 16, 2018 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, contact Fatima Rizvi, PharmD, Regulatory Project Manager, at (240) 402-7426 or at Fatima.Rizvi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Supervisory Associate Director
Division of Oncology Products 1
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/

LALEH AMIRI KORDESTANI
09/24/2019 03:34:24 PM