NDA 211651/S-006

**SUPPLEMENT APPROVAL**
**FULFILLMENT OF POSTMARKETING COMMITMENT**

Pfizer Inc.,
Attention: Mindy Sperling Mercado
Director, Pfizer Global Regulatory Affairs
100 Cambridge Park Drive, Suite 505
Cambridge, MA 02140

Dear Ms. Sperling Mercado:

Please refer to your supplemental new drug application (sNDA) dated March 13, 2020, received March 13, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Talzenna (talazoparib) capsules.

This Prior Approval supplemental new drug application provides for revisions to the Prescribing Information based on the final overall survival analysis from the EMBARCA 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.

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]

[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 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).

## FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated March 13, 2020, containing the final report for the following postmarketing commitment listed in the October 16, 2018, approval letter.

3476-3 Submit the final overall survival analysis with datasets and final report from EMBARCA clinical trial entitled “A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Center Study of BMN-673 versus Physician’s Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received No More than 2 Prior Chemotherapy Regimens for Metastatic Disease”

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 October 16, 2018, approval letter that is 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 Fatima Rizvi, PharmD, Regulatory Project Manager, at (240) 402-7426.

Sincerely,

*{See appended electronic signature page}*

Laleh Amiri-Kordestani, MD
Director (Acting)
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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**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.**

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/s/

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LALEH AMIRI KORDESTANI
10/22/2020 12:40:29 PM