



NDA 211651/S-013
NDA 217439/S-003

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
COMMITMENT**

Pfizer Inc.
Attention: Sharmi Patel, PharmD, MBA
Senior Manager, Global Regulatory Strategy, Oncology
66 Hudson Boulevard East
New York, NY 10001

Dear Dr. Patel:

Please refer to your supplemental new drug applications (sNDA) dated December 19, 2024, received December 19, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Talzenna (talazoparib) capsule.

This Prior Approval supplemental new drug application provides for an indication expansion of talazoparib in combination with enzalutamide to include treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), unselected for HRR mutation status.

APPROVAL & LABELING

We have completed our review of this application. The overall survival update for the existing indication for the treatment of adult patients with HRR gene-mutated mCRPC, based on the final analysis of TALAPRO-2 is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

The proposed expanded indication for the treatment of adult patients with mCRPC unselected for HRR mutations is not approved. As discussed at the Oncologic Drugs Advisory Committee meeting on May 21, 2025, the TALAPRO-2 trial was not sufficient to conclude a favorable benefit-risk profile for adding talazoparib to enzalutamide in patients with non-HRR gene-mutated mCRPC. Efficacy for these patients should be established in a clinical trial that includes adequate prospective determination of biomarker status and formal statistical testing in the biomarker-negative population.

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

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 the 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.

We are waiving the pediatric study requirement for this application as necessary studies are impossible or highly impracticable to conduct in the pediatric population since the indication rarely if ever exists in children and an adequate study population does not exist.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated, December 19, 2024, containing the final report for the following post marketing commitment listed in the June 20, 2023, approval letter for NDA 211651/S-010.

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>.

- 4460-1 Complete the trial, “A phase 3, randomized, double-blind, placebo controlled study of talazoparib with enzalutamide in metastatic castration- resistant prostate cancer (TALAPRO-2),” and include final overall survival analyses of patients with homologous recombination repair (HRR) gene-mutated (HRRm) mCRPC (including HRRm patients enrolled in Cohort 1 and Cohort 2) and patients in Cohort 1 (all-comers).

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

We remind you that there are post marketing commitments listed in the June 20, 2023, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

applicable, to the FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to the FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Christal Lee, Regulatory Project Manager, at 240-402-2711 or Christal.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Daniel Suzman, MD
Deputy Director
Division of Oncology 1
Office of Oncologic Diseases
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/

DANIEL L SUZMAN
06/12/2025 11:17:07 AM