NDA 208447/S-022
NDA 208447/S-024

SUPPLEMENT APPROVAL

GlaxoSmithKline LLC.
Attention: Alexander Polacheck, PhD
Associate Director, Regulatory Affairs
1000 Winder Street, North
Waltham, MA 02451

Dear Dr. Polacheck:

Please refer to your supplemental new drug applications (sNDAs) dated January 29, 2021 and May 27, 2021(2), received January 29, 2021 and May 27, 2021(2), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zejula (niraparib) Capsules, 100 mg.

Prior Approval supplemental new drug application 022 proposes to revise the Zejula capsule bottle label as follows:

- Redesigned to include the capsule image, and to change the color scheme to purple to conform to GSK corporate standards
- Add the previously approved March 3, 2021text for tartrazine from Supplements 19 and 20 to the bottle label
- Include the missing required technical elements (i.e., lot/expiration visuals)

Changes Being Effected supplemental new drug application 024 proposes to revise a typographical error identified in Section 6; Adverse Reactions, in Table 6, of the currently approved USPI.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed labeling.

- The minor correction was made to the renal and urinary disorders acute kidney injury row in Table 6: Adverse Reactions Reported in ≥10% of Patients Receiving ZEJULA Based on Baseline Weight or Platelet Count in PRIMA.

Actual values (approved with S-017 – PRIMA efficacy supplement, dated 29 April 2020)

Adverse Reaction	Grades 1-4		Grades 3-4	
	ZEJULA (n = 169) %	Placebo (n = 86) %	ZEJULA (n = 169) %	Placebo (n = 86) %
Renal and urinary disorders				
Acute kidney injury	12	5	1	0

Incorrect values (approved with S-019 & S-020 – Warnings & Precautions update, dosing recommendation for patients with moderate hepatic impairment, dated March 3 2021)

Adverse Reaction	Grades 1-4		Grades 3-4	
	ZEJULA (n = 169) %	Placebo (n = 86) %	ZEJULA (n = 169) %	Placebo (n = 86) %
Renal and urinary disorders				
Acute kidney injury	21	14	0	0

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 Medication Guide), 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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

[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.

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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 208447/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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.

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 Kim J. Robertson, Senior Regulatory Health Project Manager, at (301) 796-1441, or kim.robertson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
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
- Carton and Container 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/

LALEH AMIRI KORDESTANI
07/27/2021 02:28:54 PM