NDA 208558/S-018

GENERAL ADVICE

AstraZeneca Pharmaceuticals LP
Attention: Terrance Ulatowski
Director, Global Regulatory Affairs Oncology
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Ulatowski:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lynparza (olaparib) tablets.

We also refer to your July 2, 2020, submission, containing a Prior Approval Supplement to add "angioedema" to the Adverse Reactions, subsection 6.2 Postmarketing Experience of the U.S. Prescribing Information and to our Approval letter dated November 2, 2020.

We have the following comment:

> On page three of the Approval letter, "Patient Package Insert" was inadvertently listed as part of the content of labeling instead of "Medication Guide".

If you have any questions, contact Clara Lee, Regulatory Project Manager, at Clara.Lee@fda.hhs.gov or (240) 402-4809.

Sincerely,

{See appended electronic signature page}

Rajesh Venugopal, MPH, MBA
Chief, Project Management Staff
Oncology 1 Group
Division of Regulatory Operations for Oncologic Diseases
Office of Regulatory Operations
Center for Drug Evaluation and Research

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/s/

RAJESH VENUGOPAL
11/09/2020 10:24:19 AM

NDA 208558/S-018

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Terrance Ulatowski
Director, Global Regulatory Affaris Oncology
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Ulatowski:

Please refer to your supplemental new drug application (sNDA) dated and received July 2, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lynparza (olaparib) tablets.

This Prior Approval sNDA provides for addition of "angioedema" to Adverse Reactions, subsection 6.2 Postmarketing Experience of the U.S. Prescribing Information.

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 with a minor editorial revision listed below and reflected in the enclosed labeling.

- Updated the date at the end of the Highlights of Prescribing Information to "Revised: 11/2020".

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 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).

[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.

If you have any questions, contact Clara Lee, Regulatory Project Manager, at Clara.Lee@fda.hhs.gov or (240) 402-4809.

Sincerely,

{See appended electronic signature page}

Shaily Arora, PharmD.
Associate Director for Safety (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/s/

SHAILY ARORA
11/02/2020 08:43:12 AM