NDA 208558/S-012

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Suzanne Volpe, MS, RAC
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Volpe:

Please refer to your supplemental new drug application (sNDA) dated July 9, 2019, received July 9, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lynparza® (olaparib) Tablets.

This "Changes Being Effected" supplemental new drug application provides for updated container labels based on the recent approvals of Lynparza® Tablets (NDA 208558/S-006) and Lynparza® Capsules (NDA 206162/S-011).

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on July 9, 2019, 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 208558/S-012**." 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, contact Clara Lee, Regulatory Project Manager, at (240) 402-4809 or Clara.Lee@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):

- 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
10/11/2019 12:48:23 PM