



NDA 208447/S-018

## SUPPLEMENT APPROVAL

GlaxoSmithKline, Inc.  
Attention: Alexandra Polacheck, PhD  
Senior Manager, Regulatory Affairs  
1000 Winter Street, Suite 3300  
Waltham, MA 02451

Dear Dr. Polacheck:

Please refer to your supplemental new drug application (sNDA) dated May 1, 2020, received May 1, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zejula (niraparib) Capsules.

This "Changes Being Effected" supplemental new drug application provides for minor updates to the Zejula (niraparib) Capsules 30-capsules bottle label.

### **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.

### **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-018**". Approval of this submission by FDA is not required before the labeling is used.

### **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, Sr. Regulatory Health Project Manager, at (301) 796-1441.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):

- Carton and Container Labeling

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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  
05/29/2020 03:39:37 PM