December 2022

IMPORTANT PRESCRIBING INFORMATION

Subject: ZEJULA (niraparib) Important Prescribing Information for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy in second or later line setting.

Dear Health Care Provider:

This letter is to inform you about an important change to the ZEJULA® (niraparib) United States Prescribing Information (USPI) for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy received in the second or later line setting. The letter is an update to the Dear Health Care Provider letter (DHCPL) dated November 2022.

Indications

GSK restricted the indication of ZEJULA for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy received in the second or later line setting **to the g*BRCA*mut patient population only in the United States (US)** at the request of the US Food and Drug Administration (FDA) following the final overall survival (OS) analysis of the ENGOT-OV16/NOVA (NOVA) study.

Revision to the ZEJULA USPI resulting from this change became effective on 08 December 2022.

Prescriber Action

- Physicians should not initiate new treatment with ZEJULA for maintenance treatment of patients with non-g*BRCA*mut platinum sensitive recurrent high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer in the second or later line setting.

- Physicians who are currently treating patients with ZEJULA for patients with non-g*BRCA*mut platinum sensitive recurrent ovarian cancer in the second or later line maintenance setting are asked to discuss this information with those patients for an individual benefit-risk assessment so that they can make an informed decision regarding their ongoing care.

This recommendation **does not apply to the first line ZEJULA indication** for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking ZEJULA to GSK at 1-888-825-5249. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Contact for Further Information or Questions

You may contact our medical information department at 1-877-GSK-MI4U (6448) if you have any questions about the information contained in this letter or the safe and effective use of ZEJULA. This letter is not intended as a complete description of the benefits and risks related to the use of ZEJULA. Please refer to the enclosed full prescribing information.

Sincerely,

Sabine Luik, MD
Chief Medical Officer (CMO) and SVP Global Medical Regulatory & Quality
GSK

Enclosure(s): ZEJULA Full Prescribing Information