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IMPORTANT PRESCRIBING INFORMATION

Subject: Change to ZEJULA (niraparib) current 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 first-line platinum-based chemotherapy

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 advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Indications

At the request of the US Food and Drug Administration (FDA), GSK has restricted the indication of ZEJULA 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 first-line platinum-based chemotherapy **to patients with Homologous Repair Deficient (HRD; including BRCAm) positive ovarian cancer.**

This action is taken following the review of the final analysis of the PRIMA (NCT02655016) trial, including overall survival information, whereby the FDA has concluded the benefit-risk profile for the non-HRD positive patient population is no longer favorable.

Revision to the ZEJULA USPI resulting from this change became effective on date of approval.

Prescriber Action

- Physicians should not initiate new treatment with ZEJULA for maintenance treatment of patients with non-HRD positive advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in the first line setting.
- Physicians who are currently treating patients with ZEJULA for patients with non-HRD positive advanced ovarian cancer 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.

Reporting Adverse Events

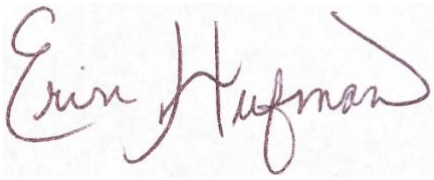
Health care providers and patients are encouraged to report adverse events in patients taking ZEJULA to GSK at 1-888-825-5249. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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,

Amy Kemner, Vice President and Therapeutic Area Head, US Medical Affairs, Oncology



Erin Hufman, Senior Vice President, Head of US Medical Affairs

Enclosure(s): ZEJULA Full Prescribing Information