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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate to you the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252-ext. 220

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PARP Inhibitors Ovarian Cancer Indications Withdrawn

Drug manufacturers have recently withdrawn their respective poly (ADP-ribose) polymerase inhibitors (PARPi) for highly pre-treated ovarian cancer patients due to safety concern.

The Withdrawals

In August, AstraZeneca voluntarily withdrew its Lynparza™ (olaparib) for the treatment of highly pre-treated patients with advanced ovarian cancer bearing *BRCA* mutations. This decision was based on a subgroup analysis of the Phase III SOLO3 trial, which found that treated patients were 33% more likely to die than comparators who received standard chemotherapy.

GlaxoSmithKline (GSK) also restricted the use of its PARP inhibitor, Zejula™ (niraparib), in ovarian cancer patients with deleterious or suspected deleterious germline *BRCA* mutations. GSK voluntarily withdrew the indication for Zejula™ for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)-positive status back in September 2022. GSK's decision was based on the potential detrimental effect on overall survival observed with other PARP inhibitors in their respective randomized, active-controlled clinical trials.

The U.S. Food & Drug Administration (FDA) has requested that Clovis Oncology limit the indication of its PARP inhibitor, Rubraca™ (rucaparib) as second-line maintenance therapy in recurrent ovarian cancer. The proposed change would limit its use to only patients harboring tumor *BRCA* mutations. In June, Clovis had voluntarily withdrawn Rubraca's indication as a third-line treatment for *BRCA*-mutated ovarian cancer. This was based on overall survival data from the ARIEL4 clinical trial that showed a 31.3% risk for death compared with chemotherapy, particularly in patients with platinum-resistant tumors.

The FDA's concerns stem from patient survival findings from the ARIEL3 trial. In patients without *BRCA* mutations and with high level of a genetic abnormality, Rubraca™ showed a 28% higher risk of death than placebo. In patients with low level of genetic abnormality, there was a 15% increased risk of death

compared to placebo. If the FDA and Clovis do not reach an agreement over the revisions, the Agency will convene a meeting of the Oncologic Drugs Advisory Committee to re-scrutinize the drug. Clovis is currently considering the FDA's request.

Each company emphasized that these withdrawals do not affect other indications for the drugs.

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