Generic Name:
Olaparib
Trade Name:
Lynparza
Company:
AstraZeneca, Merck
Notes:

AstraZeneca and Merck announced FDA approval of olaparib for maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy, as detected by an FDA-approved companion diagnostic test.

This is the first regulatory approval for a poly (ADP-ribose) polymerase (PARP) inhibitor in the first-line maintenance setting for BRCAm advanced ovarian cancer.

Approval was based on positive results from the pivotal Phase III SOLO-1 trial in which olaparib reduced the risk of disease progression or death by 70% in patients with BRCAm advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy (HR 0.30 [95% CI 0.23?0.41], P < 0.0001) compared with placebo following platinum-based chemotherapy.

The safety profile of olaparib was consistent with that of previous trials.

Medication Monitor Categories:
Supplemental Approvals