FDA Approves Lynparza for Ovarian Cancer Maintenance Therapy

PARP inhibitor slowed disease progression in SOLO-1 study.

December 21, 2018 By Food and Drug Administration (FDA)

FDA approves olaparib for first-line maintenance of BRCA-mutated advanced ovarian cancer

On December 19, 2018, the Food and Drug Administration approved olaparib (Lynparza, AstraZeneca Pharmaceuticals LP) for the 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. Patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer should be selected for therapy based on an FDA-approved companion diagnostic.

Approval was based on SOLO-1 (NCT01844986), a randomized, double-blind, placebo-controlled, multi-center trial that compared the efficacy of olaparib with placebo in patients with BRCA-mutated (BRCAm) advanced ovarian, fallopian tube, or primary peritoneal cancer following first-line platinum-based chemotherapy. Patients were randomized (2:1) to receive olaparib tablets 300 mg orally twice daily (n=260) or placebo (n=131).

The primary efficacy outcome was investigator-assessed progression-free survival (PFS) evaluated according to Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. The trial demonstrated a statistically significant improvement in investigator-assessed PFS for olaparib compared to placebo. Estimated median PFS was not reached in the olaparib arm and was 13.8 months in the placebo arm (HR 0.30; 95% CI: 0.23-0.41; $p<0.0001$). At the time of the analysis of PFS, overall survival data were not mature.

Most common (≥10%) adverse reactions of any grade occurring in patients who received olaparib in SOLO-1 were nausea, fatigue, abdominal pain, vomiting, anemia, diarrhea, upper respiratory tract infection/influenza/nasopharyngitis/bronchitis, constipation, dysgeusia, decreased appetite, dizziness, neutropenia, dyspepsia, dyspnea, urinary tract infection (UTI), leukopenia, thrombocytopenia, and stomatitis.

FDA also approved the BRACAnalysis CDx test (Myriad Genetic Laboratories, Inc.) to identify patients with germline BRCA mutated (gBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are eligible for olaparib. The effectiveness of the BRACAnalysis CDx

test was based on the SOLO-1 trial population for whom deleterious or suspected deleterious gBRCAm status was confirmed with either prospective or retrospective testing with the BRACAnalysis CDx test.

The recommended olaparib dose is 300 mg (two 150 mg tablets) taken orally twice daily, with or without food, for a total daily dose of 600 mg.

View full prescribing information for Lynparza.

The FDA Oncology Center of Excellence Assessment Aid Pilot Project was used for the review of this application.

FDA granted this application priority review. FDA expedited programs are described in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on December 19, 2018.
