FDA Approves Zejula For First-Line Maintenance of Advanced Ovarian Cancer

Zejula delayed disease progression in people with advanced ovarian cancer who had a complete or partial response to platinum chemotherapy.

April 30, 2020 By Food and Drug Administration (FDA)

On April 29, 2020, the Food and Drug Administration approved niraparib (ZEJULA, GlaxoSmithKline) 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.

Efficacy was investigated in PRIMA (NCT02655016), a double-blind, placebo-controlled trial that randomized 733 patients to niraparib or matched placebo. Patients were in a complete or partial response to first-line platinum-based chemotherapy.

The main efficacy outcome measure, progression-free survival (PFS), was first tested in the homologous recombination deficient population, then in the overall population and was determined by blinded independent central review per RECIST 1.1. Tumor samples were tested for homologous recombination deficiency status; homologous recombination deficient was defined by either presence of tumor breast cancer susceptibility gene (tBRCA) mutation or genomic instability score (GIS) ≥42. An FDA-approved companion diagnostic is not required to initiate treatment with ZEJULA for this indication.

The trial demonstrated a statistically significant improvement in PFS for patients randomized to niraparib compared with placebo in the homologous recombination deficient and overall population. Median PFS in the homologous recombination deficient population was 21.9 months (19.3, NE) for patients receiving niraparib compared with 10.4 months (8.1, 12.1) for those receiving placebo (HR 0.43; 95% CI: 0.31, 0.59; p<0.0001). Median PFS in the overall population was 13.8 months (11.5, 14.9) for patients receiving niraparib compared with 8.2 months (7.3, 8.5) for those receiving placebo (HR 0.62; 95% CI: 0.50, 0.76; p<0.0001).

The most common adverse reactions in ≥10% of all patients receiving niraparib in the PRIMA trial were thrombocytopenia, anemia, nausea, fatigue, neutropenia, constipation, musculoskeletal pain, leukopenia, headache, insomnia, vomiting, dyspnea, decreased appetite, dizziness, cough,

hypertension, AST/ALT elevation, and acute kidney injury.

The recommended niraparib dose for first-line maintenance treatment of advanced ovarian cancer is based on body weight or platelet count. For patients weighing less than 77 kg (170 lbs) OR with a platelet count of less than 150,000/µL, the recommended dose is 200 mg taken orally once daily. For patients weighing greater than or equal to 77 kg (170 lbs) AND who have a platelet count greater than or equal to 150,000/µL, the recommended dose is 300 mg taken orally once daily.

View full prescribing information for ZEJULA.

This review used the Real-Time Oncology Review (RTOR), which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. This application was approved 2 months prior to the FDA goal date.

This application was granted priority review. A description of FDA expedited programs is 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 April 29, 2020.
