FDA Approves Zejula for Advanced Ovarian Cancer in People With Faulty DNA Repair Genes

The indication is for people with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens.

October 23, 2019 By Food and Drug Administration (FDA)

FDA approves niraparib for HRD-positive advanced ovarian cancer

On October 23, 2019, the Food and Drug Administration approved niraparib (ZEJULA, Tesaro, Inc.) for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)-positive status. HRD is defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability in patients with disease progression greater than six months after response to the last platinum-based chemotherapy.

Efficacy was investigated in 98 patients with advanced ovarian cancer with HRD-positive tumors in the single-arm QUADRA (NCT02354586) trial. Patients were treated with three or more prior lines of chemotherapy. Patients with prior exposure to PARP inhibitors were excluded. Patients without BRCA mutations must have progressed at least six months after the last dose of platinum-based therapy. HRD-positive status was determined using the Myriad myChoice CDx as either tumor BRCA mutated (tBRCAm) (n=63) and/or a genomic instability score (GIS) ≥ 42 (n=35). All patients received 300 mg of niraparib once daily until disease progression or unacceptable toxicity

The primary efficacy outcome measures were objective response rate (ORR) and duration of response (DOR), as assessed by the investigator using RECIST 1.1. In the 98 patients in the HRD-positive cohort, ORR was 24% (95% CI: 16, 34). All were partial responses. Estimated median DOR was 8.3 months (95% CI: 6.5, not estimable).

For patients with tBRCAm ovarian cancer, ORR was 39% (7/18; 95% CI: 17, 64) in patients with platinum-sensitive disease, 29% (6/21; 95% CI: 11, 52) in those with platinum-resistant disease, and 19% (3/16; 95% CI: 4, 46) in patients with platinum-refractory disease.

Adverse reactions led to dose reduction or interruption in 73% of patients receiving niraparib in QUADRA. The most common adverse reactions (≥5%) resulting in dose reduction or interruption were thrombocytopenia (40%), anemia (21%), neutropenia (11%), nausea (13%), vomiting (11%),

fatigue (9%), and abdominal pain (5%).

The recommended niraparib dose is 300 mg taken once daily with or without food. Patients should be selected for therapy based on an FDA-approved companion diagnostic for niraparib.

View full prescribing information for ZEJULA.

The FDA also approved the Myriad myChoice CDx test for determination of tumor HRD status to select patients for niraparib.

View information on the FDA-approved test for the detection of deleterious or suspected deleterious BRCA mutation and/or genomic instability for this indication.

FDA granted this application 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.

Check out recent approvals at the OCE's podcast, Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.)

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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