Zejula® (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) 1 and PARP 2 inhibitor that is now approved as a maintenance treatment in the first-line setting for women with advanced ovarian cancer who responded to platinum-based chemotherapy regardless of biomarker status.1

PRIMA Study Design

In a Phase 3, double-blind, placebo-controlled 3-arm study conducted in 30 countries across 181 sites, designed to assess whether Zejula as a maintenance treatment would increase progression-free survival in the first-line therapy of women with Stage II or IV ovarian cancer who responded to platinum-based chemotherapy.

The primary endpoint was progression-free survival in patients, regardless of biomarker status.

Overall survival was a key secondary endpoint. Other secondary endpoints included the time until the first subsequent therapy, progression-free survival 2 and pharmacodynamic analyses, and patient-reported outcomes.

Key Findingsii,iii

Zejula® in combination with known newly diagnosed advanced ovarian cancer who had a response to platinum-based chemotherapy, Zejula demonstrated statistically significant improvement in progression-free survival regardless of biomarker status. Among all patients, Zejula resulted in a 38% relative risk decrease in the risk of disease progression or death vs. placebo (HR 0.62; 95% CI 0.50 to 0.76; p<0.001).

In an exploratory analysis, Patient-Reported Outcome quality of life was consistent between Zejula® and placebo.

Zejula® (niraparib) Indication and Important Safety Information

Indications

First-line Maintenance Advanced Ovarian Cancer

Zejula is indicated for:

• for the maintenance treatment of adult patients with advanced, platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer who have responded to platinum-based chemotherapy.
• in women with advanced ovarian cancer who have responded to platinum-based chemotherapy.

• for the maintenance treatment of adult patients with advanced, platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer.
• in women with advanced ovarian cancer who have responded to platinum-based chemotherapy.

Please see accompanying Prescribing Information.

• for the maintenance treatment of adult patients with advanced, platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer who have responded to platinum-based chemotherapy.

• for the maintenance treatment of adult patients with advanced, platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.

• genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.
• a deleterious or suspected deleterious BRCA mutation, or

Common clinical laboratory abnormalities (Grades 1-4)

The most common adverse reactions in ≥10% of patients who received ZEJULA in QUADRA were nausea (67%), fatigue (56%), vomiting (44%), constipation (36%), abdominal pain (34%), musculoskeletal pain (39%), decreased appetite (19%), dizziness (19%), increased AST/ALT (27%), and increased creatinine (17%).

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in NOVA were nausea (74%), thrombocytopenia (52%), anemia (51%), vomiting (44%), constipation (36%), abdominal pain (34%), musculoskeletal pain (39%), decreased appetite (19%), dizziness (19%), increased AST/ALT (27%), and increased creatinine (17%).

Important Information

Hematologic

Common adverse reactions in ≥10% of patients who received ZEJULA in QUADRA included anemia (35%), neutropenia (28%), thrombocytopenia (27%), and decreased platelet count (24%).

Common adverse reactions in ≥10% of patients who received ZEJULA in NOVA included anemia (31%), neutropenia (28%), thrombocytopenia (27%), and decreased platelet count (24%).

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in PRIMA included anemia (36%), neutropenia (31%), thrombocytopenia (28%), and decreased platelet count (24%).

Hypertension

Common adverse reactions in ≥10% of patients who received ZEJULA in QUADRA included hypertension (15%), increased AST (15%), and increased ALT (14%).

Common adverse reactions in ≥10% of patients who received ZEJULA in NOVA included hypertension (13%), increased AST (14%), and increased ALT (14%).

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in PRIMA included hypertension (20%), increased AST (18%), and increased ALT (18%).

Diabetes Mellitus

Common adverse reactions in ≥10% of patients who received ZEJULA in QUADRA included diabetes mellitus (9%), diabetic ketoacidosis (4%), and diabetic ketoacidosis (4%).

Common adverse reactions in ≥10% of patients who received ZEJULA in NOVA included diabetes mellitus (7%), diabetic ketoacidosis (4%), and diabetic ketoacidosis (4%).

The most common adverse reactions in ≥10% of patients who received ZEJULA in PRIMA included diabetes mellitus (17%), diabetic ketoacidosis (10%), and diabetic ketoacidosis (10%).

In QUADRA, the incidence of grade 3 or 4 hematologic adverse reactions was increased in patients who received ZEJULA compared to patients who received placebo, with discontinuation rates of 2%, 2%, and 2% for platelet count, white blood cell count, and absolute neutrophil count, respectively.

Zejula demonstrated significant statistically significant improvement in progression-free survival regardless of biomarker status. Among all patients, Zejula resulted in a 38% relative risk decrease in the risk of disease progression or death vs. placebo (HR 0.62; 95% CI 0.50 to 0.76; p<0.001).

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