Zejula™
niraparib
capsules 100 mg

Now Approved

TESARO is proud to announce that ZEJULA is now approved as once-daily oral maintenance treatment for patients with recurrent ovarian cancer.[1]

You are invited to attend a review of the Prescribing Information for ZEJULA

Presented by

Oliver Dorigo, MD, PhD

Director and Associate Professor, Division Gynecologic Oncology
Director, Gynecologic Oncology Clinical Care Program, Stanford Women's Cancer Center, Department of Obstetrics and Gynecology

Tuesday, November 7, 2017
6:00 PM

Le Papillon
410 Saratoga Avenue
San Jose, CA 95129

Limited seating is available. Please RSVP to Lori Leonard by November 6, 2017, at: **lleonard@tesarobio.com or 415-509-2092**.

Attendees may opt out of the meal by indicating so in their RSVP.

Indication

ZEJULA is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Please see Important Safety Information on the reverse side and accompanying full Prescribing Information, also available at ZEJULA.com.

Tesaro is committed to complying with all applicable laws and regulations and adhering to the highest standards in its interactions with healthcare professionals. Minnesota, Vermont, the Department of Defense, and the Department of Veteran Affairs have regulations or policies that prohibit the receipt of meals at company sponsored events. You are accountable for understanding such restrictions and complying with them. Tesaro may restrict your participation in this program. Please note, per industry guidelines, we are unable to accommodate spouses or guests at this event. The invitation is nontransferable and is for relevant healthcare professionals only. In order to ensure accurate transparency reporting of meals, Tesaro requires program attendees to sign in upon arrival. Subject to all applicable federal and/or state regulations Tesaro will disclose information related to meals provided to you. In most cases, this information will be made public. Attendees may opt out of the meal by indicating on their RSVP.

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Important Safety Information

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in 1.4% of patients receiving ZEJULA vs 1.1% of patients receiving placebo in Trial 1 (NOVA), and 0.9% of patients treated with ZEJULA in all clinical studies. The duration of ZEJULA treatment in patients prior to developing MDS/AML varied from <1 month to 2 years. All patients had received prior chemotherapy with platinum and some had also received other DNA damaging agents and radiotherapy. Discontinue ZEJULA if MDS/AML is confirmed.

Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients receiving ZEJULA. Grade ≥3 thrombocytopenia, anemia and neutropenia were reported in 29%, 25%, and 20% of patients receiving ZEJULA, respectively. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, in 3%, 1%, and 2% of patients, respectively. Do not start ZEJULA until patients have recovered from hematological toxicity caused by prior chemotherapy (≤ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically thereafter. If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA, and refer the patient to a hematologist for further investigations.

Hypertension and hypertensive crisis have been reported in patients receiving ZEJULA. Grade 3-4 hypertension occurred in 9% of patients receiving ZEJULA vs 2% of patients receiving placebo in Trial 1, with discontinuation occurring in <1% of patients. Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Manage hypertension with antihypertensive medications and adjustment of the ZEJULA dose, if necessary.

Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months after receiving their final dose. Because of the potential for serious adverse reactions from ZEJULA in breastfed infants, advise lactating women to not breastfeed during treatment with ZEJULA and for 1 month after receiving the final dose.

In clinical studies, the most common adverse reactions (Grades 1-4) in ≥10% of patients included: thrombocytopenia, anemia, neutropenia, leukopenia, palpitations, nausea, constipation, vomiting, abdominal pain/distention, mucositis/stomatitis, diarrhea, dyspepsia, dry mouth, fatigue/asthenia, decreased appetite, urinary tract infection, aspartate aminotransferase (AST)/alanine aminotransferase (ALT) elevation, myalgia, back pain, arthralgia, headache, dizziness, dysgeusia, insomnia, anxiety, nasopharyngitis, dyspnea, cough, rash and hypertension.

Common lab abnormalities (Grades 1-4) in ≥25% of patients included: decrease in hemoglobin, decrease in platelet count, decrease in white blood cell count, decrease in absolute neutrophil count, increase in AST and increase in ALT.

Please see accompanying full Prescribing Information, also available at ZEJULA.com.

Reference: 1. ZEJULA [package insert]. Waltham, MA: TESARO, Inc; 2017.

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