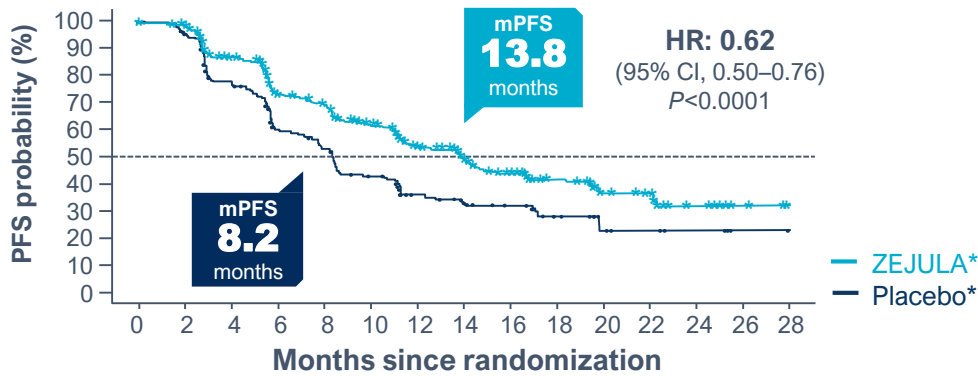


**ZEJULA: THE FIRST AND ONLY ONCE-DAILY, ORAL MONOTHERAPY FOR PLATINUM-RESPONSIVE
ADVANCED OVARIAN CANCER¹⁻³**

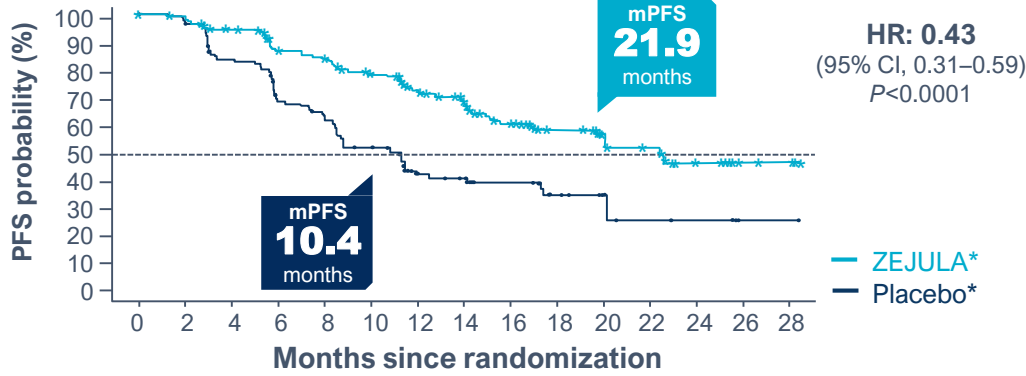


In the PRIMA trial, ZEJULA significantly improved PFS in newly diagnosed patients who responded to platinum-based chemotherapy, regardless of biomarker status¹

PFS in the overall population (N=733)



PFS in the HRd population (n=373)



Study Design^{1,4}: PRIMA, a randomized double-blind, placebo-controlled phase 3 trial, evaluated the safety and efficacy of ZEJULA in women (N=733) with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer following CR or PR to first-line platinum-based chemotherapy. Patients were randomized 2:1 to receive ZEJULA or placebo once daily. The primary endpoint was PFS in patients who had tumors that were HRd and in those in the overall population, as determined on hierarchical testing. PFS was measured from time of randomization to time of disease progression or death. Patients were stratified based on neoadjuvant chemotherapy administered (yes or no), best response to 1st platinum therapy (CR or PR) and homologous-recombination (HR) status (deficient [HR-deficient], proficient [HR-proficient], or not determined). At the time of PFS analysis, limited overall survival data were available with 11% deaths in the overall population.

Indication

ZEJULA is indicated 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.

Important Safety Information

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in 15 patients (0.8%) out of 1785 patients treated with ZEJULA monotherapy in clinical trials. The duration of therapy in patients who developed secondary MDS/cancer therapy-related AML varied from 0.5 months to 4.9 years. These patients had received prior chemotherapy with platinum agents and/or other DNA-damaging agents including radiotherapy. Discontinue ZEJULA if MDS/AML is confirmed.

Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients receiving ZEJULA. In PRIMA, the overall incidence of Grade ≥3 thrombocytopenia, anemia and neutropenia were reported, respectively, in 39%, 31%, and 21% of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients. In patients who were administered a starting dose of ZEJULA based on baseline weight or platelet count, Grade ≥3 thrombocytopenia, anemia and neutropenia were reported, respectively, in 22%, 23%, and 15% of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 3%, 3%, and 2% of patients. 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, 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.

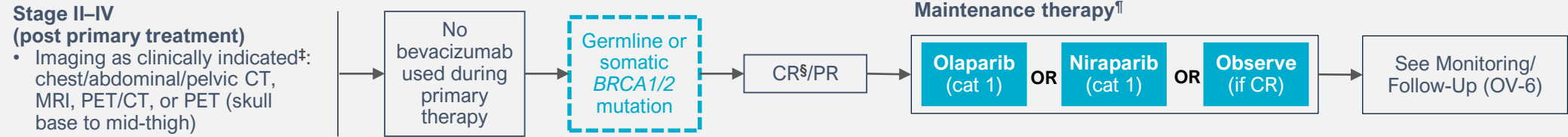
Please see additional Important Safety Information throughout, as well as the accompanying Prescribing Information.

* Censored subjects are indicated by circles or asterisks.

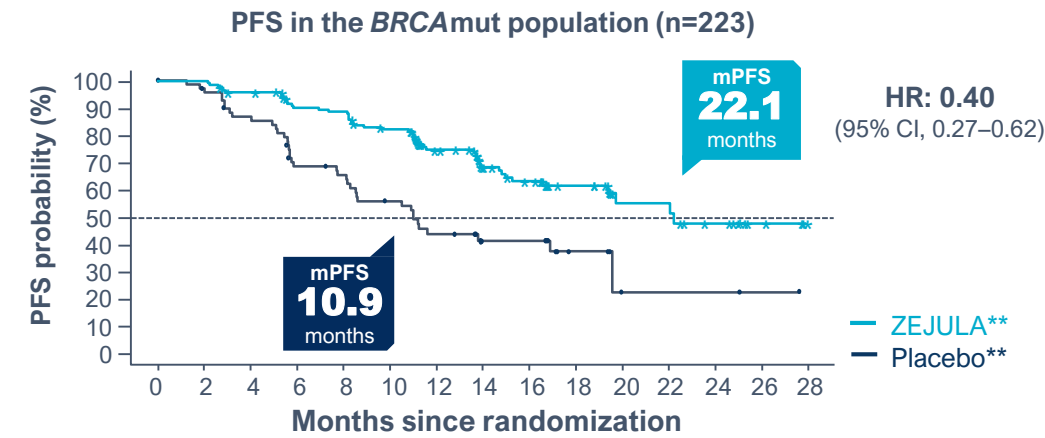
AML = acute myeloid leukemia;; CI = confident interval; CR = complete response; HR = hazard ratio; HRd = homologous recombinant deficient; MDS = myelodysplastic syndrome; mPFS = median progression-free survival; PFS = progression-free survival; PR = partial response.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for ovarian cancer include a **category 1 recommendation*** for niraparib (ZEJULA) as a single-agent option for maintenance therapy for patients in complete or partial response after surgery and platinum-based first-line chemotherapy for advanced ovarian cancer with germline or somatic *BRCA* 1/2 mutations and no bevacizumab used during primary therapy†⁵

For epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer with no bevacizumab used during primary therapy and a germline or somatic *BRCA* 1/2 mutation:



A 60% reduction in the risk of disease progression or death compared with placebo was observed in a prespecified exploratory analysis of the *BRCA*mut subgroup (n=223)^{4,6}



Among the subgroup of patients with HRnd (n=101)^{††}:

- HR: 0.85 (95% CI, 0.51–1.43)

This analysis is exploratory in nature and was not powered to detect a statistically significant treatment effect; therefore, results should be interpreted with caution.

Important Safety Information (continued)

Hypertension and hypertensive crisis have been reported in patients receiving ZEJULA. In PRIMA, Grade 3–4 hypertension occurred in 6% of patients receiving ZEJULA vs 1% of patients receiving placebo, with no reported discontinuations. Monitor blood pressure and heart rate at least weekly for the first two months, then 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.

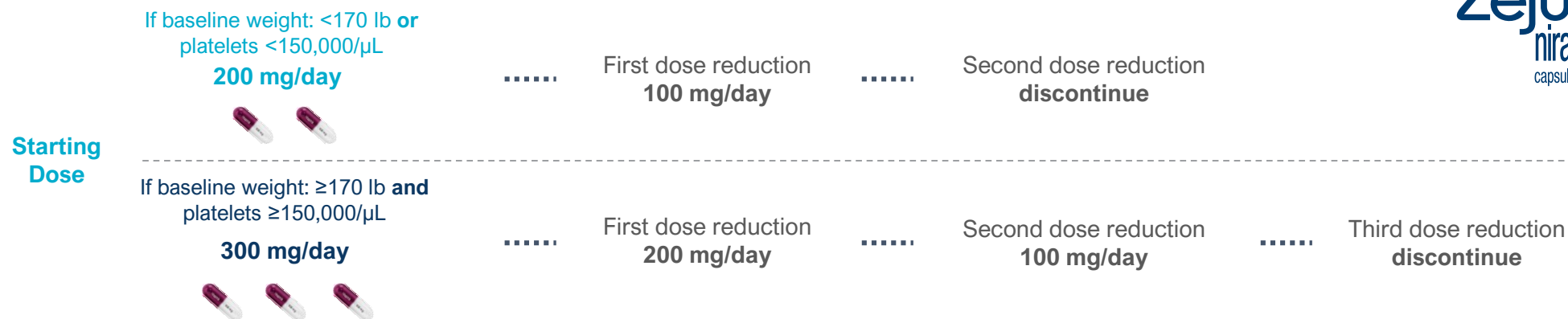
Embryo-Fetal Toxicity and Lactation: Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months after receiving their final dose of ZEJULA. Because of the 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.

Please see additional Important Safety Information throughout, as well as the accompanying Prescribing Information.

* Category 1: based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. † All recommendations are category 2A unless otherwise indicated. ‡ Imaging performed with contrast unless contraindicated. § No definitive evidence of disease. ¶ Data are limited for maintenance therapy with a PARP inhibitor for patients with stage II disease. ** Censored subjects are indicated by circles or asterisks. †† If test results were inconclusive or the test was not done, tumors were considered as homologous recombination status not determined (HRnd).

BRCA = breast cancer susceptibility gene; *BRCA*mut = *BRCA* mutated; cat = category; CI = confidence interval; CR = complete clinical remission; CT = computed tomography; HR = hazard ratio; HRnd = homologous recombination status not determined; mPFS = median progression-free survival; MRI = magnetic resonance imaging; NCCN = National Comprehensive Cancer Network; PARP = poly(ADP-ribose) polymerase; PET = position emission tomography; PFS = progression-free survival; PR = partial remission.

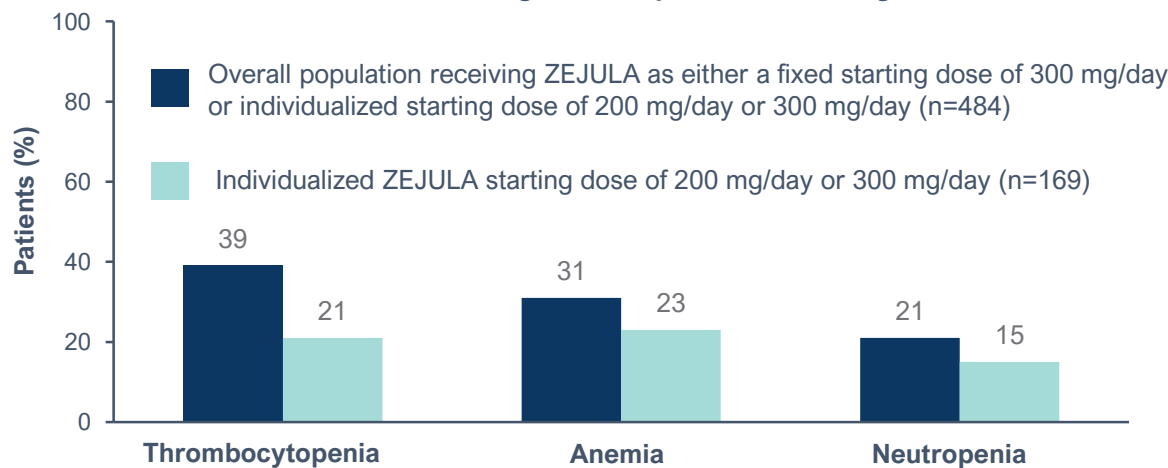
Starting dose for 1L maintenance is based on baseline body weight and platelet count¹



Lower rates of select hematologic adverse reactions were observed with an individualized starting dose¹

PRIMA prospectively evaluated the safety and efficacy of an individualized starting dose of either 200 mg or 300 mg selected based on baseline weight and platelet count, as well as a fixed starting dose of 300 mg

Select Grade 3-4 hematologic ARs in patients receiving ZEJULA



The individualized starting dose was shown to be effective in exploratory subgroup analyses* and is the approved starting dose for ZEJULA in 1L maintenance

HR 0.68 (95% CI, 0.48–0.97) in the overall population (n=258)
HR 0.39 (95% CI, 0.22–0.72) in the HRd population (n=130)

*** These analyses are exploratory in nature and did not control for Type 1 error and are not powered to determine treatment effect in any subgroup**

- Rates of Grade 3–4 leukopenia were the same in the overall and individualized starting dose populations

Important Safety Information (continued)

The most common adverse reactions (Grades 1-4) in \geq 10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (64%), nausea (57%), fatigue (51%), neutropenia (42%), constipation (40%), musculoskeletal pain (39%), leukopenia (28%), headache (26%), insomnia (25%), vomiting (22%), dyspnea (22%), decreased appetite (19%), dizziness (19%), cough (18%), hypertension (18%), AST/ALT elevation (14%), and acute kidney injury (12%).

Common lab abnormalities (Grades 1-4) in \geq 25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (87%), decreased platelets (74%), decreased leukocytes (71%), increased glucose (66%), decreased neutrophils (66%), decreased lymphocytes (51%), increased alkaline phosphatase (46%), increased creatinine (40%), decreased magnesium (36%), increased AST (35%) and increased ALT (29%).

Please see reverse side for Important Safety Information, as well as the accompanying Prescribing Information.

ALT = alanine aminotransferase; AR = adverse reaction; AST = aspartate aminotransferase; CI = confidence interval; HR = hazard ratio; HRd = homologous recombination deficient; L = line.



Proven efficacy regardless of biomarker status^{1,4}

- **Overall population:** median PFS of 13.8 months for ZEJULA vs 8.2 months for placebo (HR 0.62; 95% CI, 0.50–0.76)
- **HRd population:** median PFS of 21.9 months for ZEJULA vs 10.4 months for placebo (HR 0.43; 95% CI, 0.31–0.59)



Extends PARP inhibitor therapy to more women¹⁻³

- No companion diagnostic is required to initiate 1L therapy¹
- Testing may provide useful prognostic information and inform hereditary risk^{4,7}



Convenient, once-daily, oral monotherapy¹



Well-characterized safety profile^{1,4}

- 12% discontinuation rate due to ARs
- Lower rates of select Grade 3–4 hematologic ARs observed with individualized starting dose

Important Safety Information (continued)

Highlights of Important Safety Information: Summary of Warnings and Precautions

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to ZEJULA, and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed.

Bone Marrow Suppression: Test complete blood counts weekly for the first month, monthly for the next 11 months and periodically thereafter for clinically significant changes.

Cardiovascular Effects: Monitor blood pressure and heart rate at least weekly for the first two months, then monthly for the first year, and periodically thereafter during treatment with ZEJULA. Manage with antihypertensive medications as well as adjustment of the ZEJULA dose, if necessary.

Embryo-Fetal Toxicity: ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

Please see additional Important Safety Information throughout, as well as the accompanying Prescribing Information.

AML = acute myeloid leukemia; AR = adverse reaction; CI = confident interval; HR = hazard ratio; HRd = homologous recombinant deficient; L = line; MDS = myelodysplastic syndrome; PARP = poly(ADP-ribose) polymerase; PFS = progression-free survival.

References: 1. ZEJULA (niraparib) capsules. Prescribing Information. GlaxoSmithKline; April 2020. 2. LYNPARZA (olaparib) tablets. Prescribing Information. AstraZeneca Pharmaceuticals LP; May 2020. 3. RUBRACA (rucaparib) tablets. Prescribing Information. Clovis Oncology, Inc.; May 2020. 4. González-Martín A, et al. *N Engl J Med*. 2019;381:2391-402. 5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed May 21, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 6. Monk BJ, et al. Oral presentation at SGO 2020. 7. Konstantinopoulos PA, et al. *J Clin Oncol*. 2020;38:1222-45.

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NRPBROC200003 July 2020
Produced in USA. 0002-0007-56