FOR 1L MAINTENANCE TREATMENT OF ADULT PATIENTS WITH HRD-POSITIVE PLATINUM-RESPONSIVE ADVANCED OVARIAN CANCER[1]

1 DAILY DOSE

Zejula niraparib tablets 100/200/300 mg

ZEJULA Offers an Individualized Starting Dose[1,a]

[a]Individualized starting dose of 200 mg or 300 mg once daily is based on baseline body weight and platelet count.[1]

An exploratory analysis showed that an individualized starting dose was observed to lower rates of select ARs while maintaining efficacy[1-3]

PRIMA was a double-blind, placebo-controlled trial in which patients (N = 733) in complete or partial response to first-line platinum-based chemotherapy were randomized 2:1 to ZEJULA or matched placebo. Efficacy was evaluated in 373 patients in the HRD-positive population.[1,4,5] PFS in the HRD-positive population was the primary endpoint evaluated by BICR, per RECIST v1.1, in the primary analysis (13.8-month follow-up). **HRD-positive population (n = 373):** median PFS with ZEJULA was 21.9 months (95% CI, 19.3-NE) vs 10.4 months (95% CI, 8.1-12.1) with placebo; HR, 0.43 (95% CI, 0.31-0.59, *P*<0.0001).[1,4]

PRIMA prospectively evaluated the safety and efficacy of an individualized starting dose (n = 86) of either 200 mg or 300 mg, selected based on baseline weight and platelet count, as well as a fixed starting dose (n = 159) of 300 mg regardless of body weight or platelet count.[1,4] In patients taking an individualized starting dose, comparable efficacy was observed as measured by the HR for PFS. **HRD-positive population (n = 130):** HR, 0.39 (95% CI, 0.22-0.72)[1]; ***BRCA*m population (n = 53):** HR, 0.29 (95% CI, 0.13-0.67).[3] **These prespecified subgroup analyses were exploratory and not powered to detect a statistically significant treatment effect. Interpret results with caution.**

In the HRD-positive population, compared with patients who received either the fixed starting dose or the individualized starting dose (n = 245), ZEJULA's individualized starting dose (n = 86) was shown to reduce rates of Grade 3-4 anemia from 31% to 22%; thrombocytopenia from 38% to 16%; and neutropenia from 17% to 13%.[1]

INDICATION

ZEJULA is indicated for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) – positive status defined by either a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability. Select patients for therapy based on an FDA-authorized companion diagnostic for ZEJULA.

IMPORTANT SAFETY INFORMATION

Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), including cases with a fatal outcome, have been reported in patients who received ZEJULA. In PRIMA, of patients within the HRD-positive population, MDS/AML occurred in 8 out of 245 (3.3%) patients treated with ZEJULA, and in 3 out of 125 (2.4%) patients treated with placebo with a follow-up of 6.1 years. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 5.5 months to 5 years. All patients who developed secondary MDS/cancer therapy-related AML had received previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy. For suspected MDS/AML or prolonged hematological toxicities, refer the patient to a hematologist for further evaluation. Discontinue ZEJULA if MDS/AML is confirmed.

1L, first-line; **AR**, adverse reaction; **BICR**, blinded independent central review; ***BRCA*m**, breast cancer susceptibility gene mutated; **CI**, confidence interval; **HR**, hazard ratio; **HRD**, homologous recombination deficient; **NE**, not estimable; **PFS**, progression-free survival; **RECIST**, Response Evaluation Criteria in Solid Tumors.

Please see additional Important Safety Information throughout and the full Prescribing Information for ZEJULA at ZEJULAHCP.com.

1 DAILY DOSE

Zejula niraparib tablets 100/200/300 mg

How do you approach initiating ZEJULA in each appropriate patient?

Start treatment

1X DAILY

ZEJULA is the ONLY oral, once-daily, PARPi monotherapy for patients with HRD-positive advanced ovarian cancer[1,6,7]

For patients with complete or partial response to first-line platinum-based chemotherapy[1]

At the right time

CALENDAR 12 weeks

Wait to start ZEJULA until patients recover from hematological toxicity caused by previous chemotherapy[1]

Start ZEJULA no later than 12 weeks after your patients' most recent platinum-containing regimen[1]

With the right dose

Start your patients on ZEJULA with an individualized starting dose in 1L maintenance treatment[1]

200 mg/day

If baseline weight <170 lb OR platelets <150,000/µL

300 mg/day

If baseline weight ≥170 lb AND platelets ≥150,000/µL

Continue treatment with ZEJULA until disease progression or unacceptable toxicity.[1]

For patients with moderate hepatic impairment,[a] the recommended dosage of ZEJULA is 200 mg once daily, regardless of body weight or platelet count. Monitor patients for hematologic toxicity and reduce the dose, if needed.[1]

[a]Total bilirubin ≥1.5 to 3 x ULN and any AST level.[1] As defined by the National Cancer Institute-Organ Dysfunction Working Group (NCI-ODWG) criteria.

There are no data in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease undergoing hemodialysis.[1] No dose adjustment necessary for mild hepatic impairment (total bilirubin <1.5 x ULN and any AST level or bilirubin ≤ULN and AST >ULN) and for age ≥65 years.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

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

1L, first-line; **AST**, aspartate aminotransferase; **HRD**, homologous recombination deficient; **PARPi**, poly (ADP-ribose) polymerase inhibitor; **ULN**, upper limit of normal.

Please see additional Important Safety Information throughout and the full Prescribing Information for ZEJULA at ZEJULAHCP.com.

How can ongoing monitoring help patients stay ahead of adverse reactions?

Monitoring complete blood counts, blood pressure, and heart rate helps identify the need to dose modify[1]

	ONCE A WEEK	ONCE A MONTH	ONCE EVERY 2-3 MONTHS
BLOOD COUNTS	1ST MONTH	REST OF YEAR	AFTER YEAR 1[a]: MONITOR PERIODICALLY
BLOOD PRESSURE AND HEART RATE	1ST AND 2ND MONTHS	REST OF YEAR	AFTER YEAR 1[a]: MONITOR PERIODICALLY

If myelodysplastic syndrome or acute myeloid leukemia (MDS/AML) is confirmed, discontinue ZEJULA.[1]

[a]Monitor periodically. Per physician discretion.

How should you modify your patients' dose when they experience adverse reactions?

To manage adverse reactions, consider interruption of treatment, dose reduction, or dose discontinuation[1,b]

If baseline weight <170 lb OR platelets <150,000/µL

200 mg/day

First dose reduction: 100 mg/day

Second dose reduction: discontinue

If baseline weight ≥170 lb AND platelets ≥150,000/µL

300 mg/day

First dose reduction: 200 mg/day

Second dose reduction: 100 mg/day

Third dose reduction: discontinue

[b]Adverse reactions in the PRIMA study led to dose reduction or interruption in 79% of patients, most frequently (>10%) from thrombocytopenia (53%), anemia (32%), and neutropenia (19%).[1]

For patients with moderate hepatic impairment,[c] the recommended dosage of ZEJULA is 200 mg once daily, regardless of body weight or platelet count. Monitor patients for hematologic toxicity and reduce the dose, if needed.[1]

[c]Total bilirubin ≥1.5 to 3 x ULN and any AST level.[1] As defined by the National Cancer Institute-Organ Dysfunction Working Group (NCI-ODWG) criteria.

IMPORTANT SAFETY INFORMATION (CONT'D)

Hypertension and cardiovascular effects have been reported in patients receiving ZEJULA. Grade 3-4 hypertension occurred in 6% of patients receiving ZEJULA vs 1% of patients receiving placebo in PRIMA, 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.

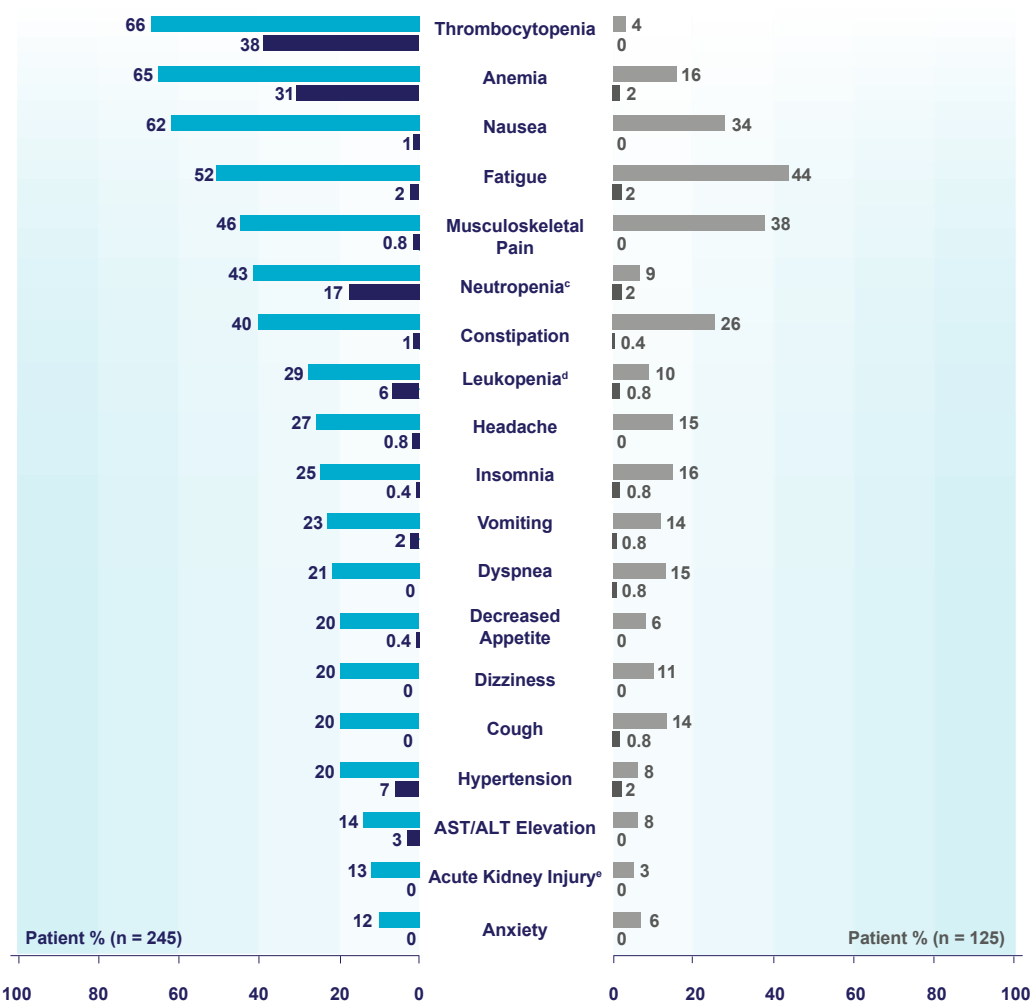
AST, aspartate aminotransferase; **ULN**, upper limit of normal.

Please see additional Important Safety Information throughout and the full Prescribing Information for ZEJULA at ZEJULAHCP.com.

What adverse reactions are associated with ZEJULA?

An established safety and tolerability profile in 1L maintenance therapy of HRD-positive platinum-responsive advanced ovarian cancer

AR reported in ≥10% of all HRD-positive patients receiving ZEJULA in PRIMA[1,a]



11% **of patients discontinued treatment with ZEJULA due to ARs[1]**

ARs resulting in discontinuation in >1% of patients who received ZEJULA included thrombocytopenia (3.7%), nausea (1.6%), and anemia (1.2%).[1]

In PRIMA, no new safety signals were reported in the 6.2-year median follow-up.[5,8] TEAEs with ZEJULA vs placebo included Grade ≥3 events (70.6% vs 28.8%), and those that led to treatment discontinuation (18.0% vs 3.2%), dose reductions (71.4% vs 12.8%), dose interruption (78.8% vs 24.8%), and deaths (3.7% vs 1.6%).[8]

ARs were managed with dose interruptions and modifications.[9]

[a]All ARs consist of grouped preferred terms except for nausea, vomiting, decreased appetite, headache, and insomnia, which are single preferred terms. [b]Common Terminology Criteria for Adverse Events version 4.02. [c]Includes neutropenia, neutropenic infection, neutropenic sepsis, and febrile neutropenia. [d]Includes leukopenia, lymphocyte count decreased, lymphopenia, and white blood cell count decreased. [e]Includes blood creatinine increased, blood urea increased, acute kidney injury, and renal failure.

IMPORTANT SAFETY INFORMATION (CONT'D)

Posterior reversible encephalopathy syndrome (PRES) occurred in 0.1% of 2,165 patients treated with ZEJULA in clinical trials and has also been described in postmarketing reports. Monitor all patients for signs and symptoms of PRES, which include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. Diagnosis requires confirmation by brain imaging. If suspected, promptly discontinue ZEJULA and administer appropriate treatment. The safety of reinitiating ZEJULA is unknown.

1L, first-line; **ALT**, alanine aminotransferase; **AR**, adverse reaction; **AST**, aspartate aminotransferase; **HRD**, homologous recombination deficient; **TEAE**, treatment-emergent adverse event.

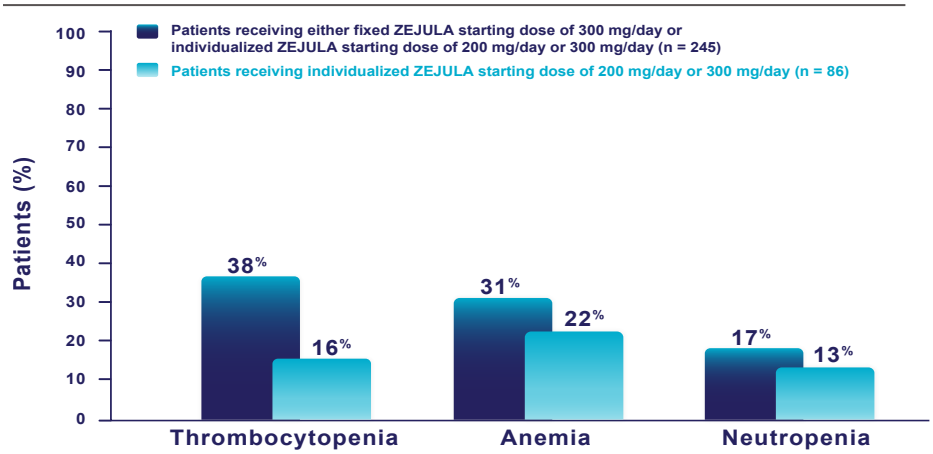
Please see additional Important Safety Information throughout and the full Prescribing Information for ZEJULA at ZEJULAHCP.com.

How does individualized starting dose impact tolerability?

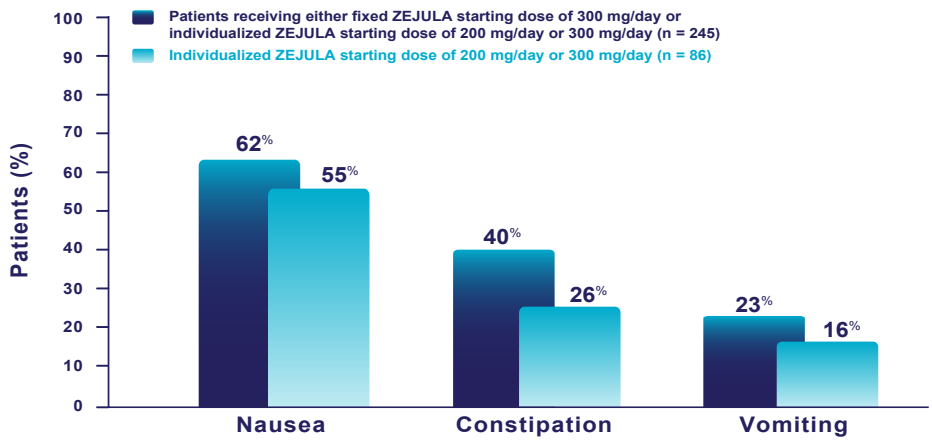
Lower rates of select hematologic and gastrointestinal adverse reactions observed with an individualized starting dose, while maintaining efficacy[1-3,a]

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[1,4,a]

Rates of select Grades 3-4 hematologic ARs in the HRD-positive population[1]



Rates of select Grades 1-4 symptomatic gastrointestinal ARs in the HRD-positive population[1]



Efficacy was maintained with the individualized starting dose[1,2,a]

- HR, 0.39 (95% CI, 0.22-0.72) in the HRD-positive population (n = 130)
- In the *BRCA*m population (n = 53), HR, 0.29 (95% CI, 0.13-0.67)[3,a]

[a]**Exploratory subgroup analysis (data cutoff: primary analysis). Not powered to detect a statistically significant treatment effect. Interpret results with caution.**

IMPORTANT SAFETY INFORMATION (CONT'D)

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 not to breastfeed during treatment with ZEJULA and for 1 month after receiving the last dose.

AR, adverse event; ***BRCA*m**, breast cancer susceptibility gene mutated; **CI**, confidence interval; **HR**, hazard ratio; **HRD**, homologous recombination deficient.

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Maintenance Treatment Matters: Start with a dose tailored to the individual patient

IMPORTANT SAFETY INFORMATION (CONT'D)

First-line Maintenance Treatment of HRD-Positive Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (65%), nausea (62%), fatigue (52%), musculoskeletal pain (46%), neutropenia (43%), constipation (40%), leukopenia (29%), headache (27%), insomnia (25%), vomiting (23%), dyspnea (21%), decreased appetite (20%), dizziness (20%), cough (20%), hypertension (20%), AST/ALT elevation (14%), acute kidney injury (13%), and anxiety (12%).

Common lab abnormalities (Grades 1-4) in ≥25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (85%), decreased leukocytes (72%), decreased platelets (71%), decreased neutrophils (64%), increased glucose (62%), decreased lymphocytes (55%), increased alkaline phosphatase (48%), increased creatinine (40%), decreased magnesium (39%), increased AST (35%), increased ALT (32%), and increased calcium (31%).

Please see the full Prescribing Information for ZEJULA at ZEJULAHCP.com.

ALT, alanine aminotransferase; **AST**, aspartate aminotransferase.

References:

1. ZEJULA (niraparib). Prescribing information. GSK; 2026. **2.** Mirza MR et al. *Cancer.* 2023;1-10. doi:10.1002/cncr.34706 **3.** Korach J et al. *Int J Gynecol Cancer.* 2020;30(suppl 4):A125-A126. doi:10.1136/ijgc-2020-ESGO.220 **4.** González-Martín A et al. *N Engl J Med.* 2019;381(25):2391-2402. doi:10.1056/NEJMoa1910962 **5.** Monk BJ et al. *Ann Oncol.* 2024;35(11):981-992. doi:10.1016/j.annonc.2024.08.2241 **6.** Lynparza (olaparib). Prescribing information. AstraZeneca Pharmaceuticals LP; 2025. **7.** Rubraca (rucaparib). Prescribing information. pharmaand GmbH; 2025. **8.** Data on file, GSK. **9.** González-Martín A et al. [supplementary appendix] *N Engl J Med.* 2019;381(25):2391-2402. doi:10.1056/NEJMoa1910962

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