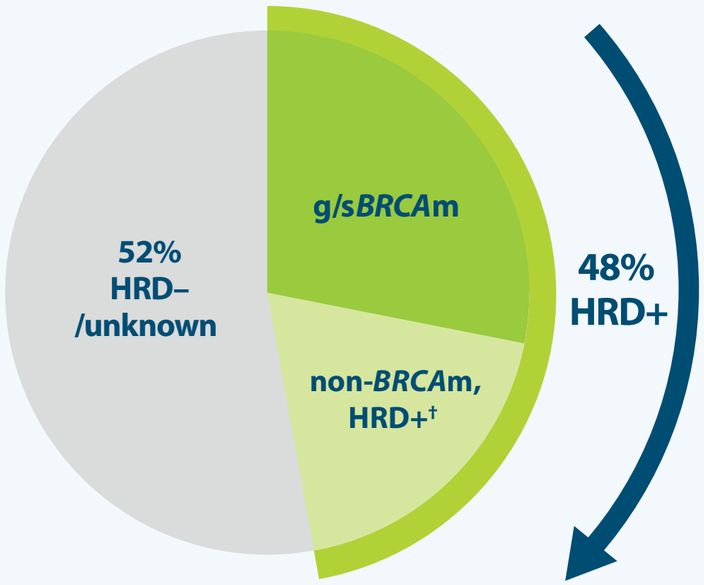
Why test for HRD?

Tumors with HRD may respond to PARPi-based regimens[1]

Lynparza®
olaparib
tablets 150 mg

PAOLA-1



In advanced ovarian cancer, ~1 in 2 women has HRD-positive disease[2-5]

The PAOLA-1 trial evaluated patients with advanced ovarian cancer in complete or partial response to first-line platinum-based chemotherapy + bevacizumab, including patients with HRD-positive* disease.[1,2]

SEE LYNPARZA DATA HERE

In the PAOLA-1 trial (n=806), all available clinical samples were retrospectively HRD tested with Myriad MyChoice® CDx[1‡]

*Select patients for this indication based on an FDA-approved companion diagnostic for LYNPARZA (Myriad MyChoice® CDx).[1]
†May include markers of genomic instability (eg, LOH, TAI, LST).[6]
‡HRD positive was defined as either a t*BRCA* mutation and/or an HRD score ≥42 by Myriad MyChoice® CDx; HRD negative was defined as non–t*BRCA*-mutated and an HRD score <42 by Myriad MyChoice® CDx.[8] 4.2% of the test results were missing, 2.1% failed, and 11.3% were inconclusive, yielding approximately 18% of the total PAOLA-1 population with an unknown HRD status.[9]

INDICATION

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

First-Line Maintenance HRD-Positive Advanced Ovarian Cancer in Combination with Bevacizumab

In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line 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-approved companion diagnostic for LYNPARZA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.2% of patients (26/2219) with various *BRCA*m, g*BRCA*m, HRR gene-mutated or HRD-positive cancers who received LYNPARZA in clinical studies as a single agent or as part of a combination regimen, consistent with the approved indications, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was approximately 2 years (range: <6 months to >4 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

In SOLO-1, patients with newly diagnosed advanced *BRCA*m ovarian cancer, the incidence of MDS/AML was 1.9% (5/260) in patients who received LYNPARZA and 0.8% (1/130) in patients who received placebo based on an updated analysis. In PAOLA-1, of patients with newly diagnosed advanced ovarian cancer with HRD-positive status, the incidence of MDS/AML was 1.6% (4/255) in patients who received LYNPARZA and 2.3% (3/131) in the control arm.

In SOLO-2, patients with *BRCA*m platinum-sensitive relapsed ovarian cancer, the incidence of MDS/AML was 8% (15/195) in patients who received LYNPARZA and 4% (4/99) in patients who received placebo. The duration of LYNPARZA treatment prior to the diagnosis of MDS/AML ranged from 0.6 years to 4.5 years.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

*BRCA*m=*BRCA*-mutated or *BRCA* mutation(s); CDx=companion diagnostic; g*BRCA*m=germline *BRCA*-mutated; HRR=homologous recombination repair; HRD=homologous recombination deficiency; LOH=loss of heterozygosity; LST=large-scale state transitions; PARPi=poly (ADP-ribose) polymerase inhibitor; s*BRCA*m=somatic *BRCA*-mutated; TAI=telomeric allelic imbalance; t*BRCA*=tumor *BRCA*.

How to test?

Test for HRD at diagnosis using Myriad MyChoice® CDx to help identify patients who may be eligible for LYNPARZA + bevacizumab

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Biomarker	Myriad MyChoice® (HRD, which includes genomic instability)[1,6*†]
gBRCA	✓
sBRCA	✓
Loss of heterozygosity (LOH)	✓
Telomeric allelic imbalance (TAI)	✓
Large-scale state transitions (LST)	✓

Did you know

➤ Gene panels without measures of genomic instability do not capture all HRD status and are not FDA-approved companion diagnostics for LYNPARZA.[1,6,10]

***Tumors with HRD include measures of genomic instability* beyond* BRCAm[1,6]**

Myriad MyChoice® is the only FDA-approved companion diagnostic for LYNPARZA, assessing tumor BRCA1/2 alterations along with a Genomic Instability Score (inclusive of LOH, TAI, and LST).[1,6,7]

*Genomic instability is measured by an aggregate score that includes assessment of all of these components.[6]

†Does not distinguish between somatic and germline on reports.[6]

‡In a molecular assay performance evaluation of 148 tumor samples from patients with non-gBRCAm aOC following response to platinum-based chemotherapy, an LOH-based assay identified 40% as HRD-positive compared with 48% using the Myriad MyChoice® CDx.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) (Cont'd):

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Including severe and fatal cases, has occurred in patients treated with LYNPARZA. In clinical studies, among patients who received LYNPARZA as a single agent or as part of a combination regimen, the incidence of pneumonitis, including fatal cases, was 1.0% (29/2851). If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and promptly assess the source of the symptoms. If pneumonitis is confirmed, discontinue LYNPARZA treatment and treat the patient appropriately.

Venous Thromboembolism (VTE): Including severe or fatal pulmonary embolism (PE), occurred in patients treated with LYNPARZA. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Hepatotoxicity, including Drug-Induced Liver Injury (DILI): Hepatotoxicity, including severe and potentially fatal cases of DILI has occurred in patients treated with LYNPARZA. Evaluate bilirubin and transaminases at baseline and throughout treatment with LYNPARZA. For patients who develop abnormal liver tests after LYNPARZA, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold LYNPARZA. Upon confirmation of DILI, discontinue LYNPARZA.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating treatment.

Females
Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

In HRD-positive advanced ovarian cancer following response to first-line platinum-based chemotherapy + bevacizumab*[1]

PAOLA-1: PFS and OS results in a prespecified exploratory subgroup[1,2,11]

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FDA approval for LYNPARZA + bevacizumab was based on a prespecified exploratory subgroup of patients with HRD-positive† tumors (n=387)[1]

Primary Endpoint: PFS[1,2]

Median PFS

LYNPARZA + bevacizumab (n=255)	bevacizumab + placebo (n=132)
37.2 months (3.1 years)	17.7 months (~1.5 years)

PFS Hazard Ratio

HR=0.33 (95% CI: 0.25–0.45)

Events, n (%): 87/255 (34%) with LYNPARZA + bevacizumab and 92/132 (70%) with bevacizumab + placebo

ITT population (n=806)

Statistically significant difference in PFS was observed for LYNPARZA + bevacizumab compared with bevacizumab + placebo.

HRD-negative subgroup (n=277)

Results from an exploratory analysis in this subgroup (HR=1.00 [95% CI: 0.75–1.34]) indicated that the clinical benefit was primarily attributed to the results seen in the HRD-positive subgroup.

Key Secondary Endpoint: OS[11]

Median OS

LYNPARZA + bevacizumab (n=255)	bevacizumab + placebo (n=132)
75.2 months (~6.3 years)	57.3 months (~4.8 years)

OS Hazard Ratio

HR=0.62 (95% CI: 0.45–0.85)

Events, n (%): 93/255 (36%) with LYNPARZA + bevacizumab and 69/132 (52%) with bevacizumab + placebo

ITT population (n=806)

Statistical significance in OS was not reached for LYNPARZA + bevacizumab compared with bevacizumab + placebo.

HRD-negative subgroup (n=277)

Results from an exploratory analysis in this subgroup (HR=1.18 [95% CI: 0.87–1.60]) indicated that the clinical benefit was primarily attributed to the results seen in the HRD-positive subgroup.

Median OS follow-up time: ~5 years (61.7 months for LYNPARZA + bevacizumab and 61.9 months for bevacizumab + placebo) DCO: March 22, 2022.[11]

Data based upon a prespecified exploratory subgroup analysis, which was not controlled for Type 1 error. HRD status was not a stratification factor in PAOLA-1. These analyses are based on Kaplan–Meier estimates.[2,3]

PAOLA-1 Study Design

*Select patients for this indication based on an FDA-approved companion diagnostic for LYNPARZA.[1]

†Including *BRCA* mutation (as determined by Myriad MyChoice® CDx) and other causes of HRD. HRD positive was defined as either a t*BRCA* mutation and/or an HRD score ≥42 by Myriad MyChoice® CDx.[6]

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—First-Line Maintenance Advanced Ovarian Cancer in Combination with Bevacizumab

Most common adverse reactions (Grades 1-4) in ≥10% of patients treated with LYNPARZA/bevacizumab and at a ≥5% frequency compared to placebo/bevacizumab in the **first-line maintenance setting** for **PAOLA-1** were: nausea (53%), fatigue (including asthenia) (53%), anemia (41%), lymphopenia (24%), vomiting (22%), and leukopenia (18%). In addition, the most common adverse reactions (≥10%) for patients receiving LYNPARZA/bevacizumab irrespective of the frequency compared with the placebo/bevacizumab arm were: diarrhea (18%), neutropenia (18%), urinary tract infection (15%), and headache (14%).

In addition, venous thromboembolism occurred more commonly in patients receiving LYNPARZA/bevacizumab (5%) than in those receiving placebo/bevacizumab (1.9%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients for LYNPARZA in combination with bevacizumab in the **first-line maintenance setting** for **PAOLA-1** were: decrease in hemoglobin (79%), decrease in lymphocytes (63%), increase in serum creatinine (61%), decrease in leukocytes (59%), decrease in absolute neutrophil count (35%), and decrease in platelets (35%).

DRUG INTERACTIONS

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

USE IN SPECIFIC POPULATIONS

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

CI=confidence interval; DCO=data cutoff; HR=hazard ratio; OS=overall survival; PFS=progression-free survival.

When to test for HRD?

Test for HRD prior to making your induction treatment decision[1,12]

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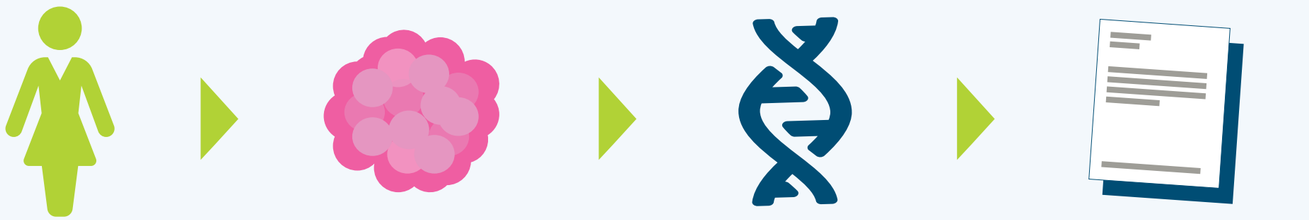

Patient presents to her doctor[13]

Collect adequate tissue sample at biopsy or surgical cytoreduction[13]

Promptly send tumor tissue to CDx lab[13]

Receive results within 2 weeks[14]

Test for HRD at diagnosis with an FDA-approved CDx to help identify patients who may be eligible for LYNPARZA + bevacizumab[1]

Consider tumor tissue sufficiency early: Collecting tissue at surgery or biopsy, prior to initiating chemotherapy, may increase the chance of yielding adequate tissue for testing[15,16]

At first tissue collection, order the Myriad MyChoice® CDx to determine patients' HRD status[1,6]

- One request form is inclusive of both the *BRCA*m and genomic instability biomarkers[1,6]
- To order Myriad MyChoice® CDx, talk to your Myriad Genetics representative or order a test kit at Myriad-Oncology.com/MyChoice-CDx

IMPORTANT SAFETY INFORMATION (Cont'd)

USE IN SPECIFIC POPULATIONS (Cont'd)

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

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In SOLO-1, patients with newly diagnosed advanced *BRCA*m ovarian cancer, the incidence of MDS/AML was 1.9% (5/260) in patients who received LYNPARZA and 0.8% (1/130) in patients who received placebo based on an updated analysis. In PAOLA-1, of patients with newly diagnosed advanced ovarian cancer with HRD-positive status, the incidence of MDS/AML was 1.6% (4/255) in patients who received LYNPARZA and 2.3% (3/131) in the control arm.

In SOLO-2, patients with *BRCA*m platinum-sensitive relapsed ovarian cancer, the incidence of MDS/AML was 8% (15/195) in patients who received LYNPARZA and 4% (4/99) in patients who received placebo. The duration of LYNPARZA treatment prior to the diagnosis of MDS/AML ranged from 0.6 years to 4.5 years.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

TEST TO TREAT: The PAOLA-1 regimen[1,6,12]

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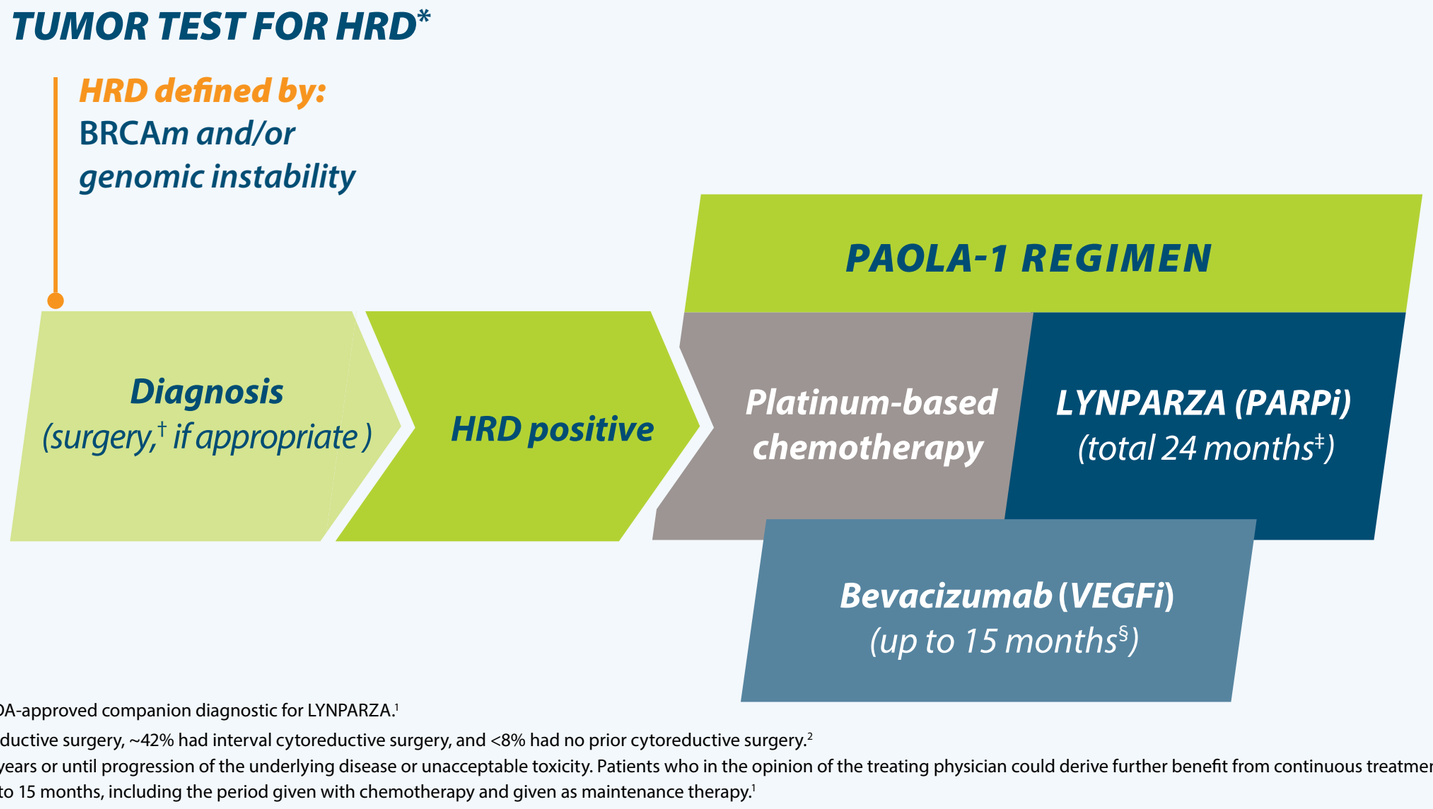

*Select patients for this indication based on an FDA-approved companion diagnostic for LYNPARZA.[1]

†In PAOLA-1, ~51% of patients had upfront cytoreductive surgery, ~42% had interval cytoreductive surgery, and <8% had no prior cytoreductive surgery.[2]

‡LYNPARZA treatment was continued for up to 2 years or until progression of the underlying disease or unacceptable toxicity. Patients who in the opinion of the treating physician could derive further benefit from continuous treatment could be treated beyond 2 years.[1]

§Bevacizumab was administered for a total of up to 15 months, including the period given with chemotherapy and given as maintenance therapy.[1]

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) (Cont'd): Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Including severe and fatal cases, has occurred in patients treated with LYNPARZA. In clinical studies, among patients who received LYNPARZA as a single agent or as part of a combination regimen, the incidence of pneumonitis, including fatal cases, was 1.0% (29/2851). If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and promptly assess the source of the symptoms. If pneumonitis is confirmed, discontinue LYNPARZA treatment and treat the patient appropriately.

Venous Thromboembolism (VTE): Including severe or fatal pulmonary embolism (PE), occurred in patients treated with LYNPARZA. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Hepatotoxicity, including Drug-Induced Liver Injury (DILI): Hepatotoxicity, including severe and potentially fatal cases of DILI has occurred in patients treated with LYNPARZA. Evaluate bilirubin and transaminases at baseline and throughout treatment with LYNPARZA. For patients who develop abnormal liver tests after LYNPARZA, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold LYNPARZA. Upon confirmation of DILI, discontinue LYNPARZA.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating treatment.

Females
Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

VEGFi=vascular endothelial growth factor inhibitor.

In women with HRD-positive advanced ovarian cancer in response to first-line platinum-based chemotherapy + bevacizumab*[1]

LYNPARZA + bevacizumab doubled mPFS vs an active comparator of bevacizumab + placebo[1]

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- *In HRD-positive patients,* ***median PFS was 37.2 months (3.1 years) with LYNPARZA + bevacizumab*** *(n=255) and 17.7 months (~1.5 years) with bevacizumab + placebo (n=132);* ***HR=0.33; 95% CI: 0.25–0.45***[1]

See the additional data, including overall survival data from a 5-year follow-up analysis, here.

- ***Adverse reactions occurring in ≥10% of patients treated with LYNPARZA + bevacizumab and at ≥5% frequency compared to bevacizumab + placebo were fatigue (including asthenia) (53% vs 32%), nausea (53% vs 22%), vomiting (22% vs 11%), anemia (41% vs 10%), lymphopenia (24% vs 9%), and leukopenia (18% vs 10%)***[1]
- ***Fatal adverse reactions occurred in 1 patient due to concurrent pneumonia and aplastic anemia. Serious adverse reactions occurred in 31% of patients who received LYNPARZA + bevacizumab. Serious adverse reactions in >5% of patients included hypertension (19%) and anemia (17%)***

- *Tumor testing for HRD at diagnosis can help identify the ~50% of women who may be eligible for LYNPARZA + bevacizumab*[1,4-6]

Learn more about LYNPARZA. Explore the data at lynparzahcp.com

*Select patients for this indication based on an FDA-approved companion diagnostic for LYNPARZA.[1]

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—First-Line Maintenance Advanced Ovarian Cancer in Combination with Bevacizumab

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In addition, venous thromboembolism occurred more commonly in patients receiving LYNPARZA/bevacizumab (5%) than in those receiving placebo/bevacizumab (1.9%).

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DRUG INTERACTIONS

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

Please see additional Important Safety Information throughout and complete Prescribing Information, including Medication Guide.

You may report side effects related to AstraZeneca products.

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2025. **2.** Ray-Coquard I, Pautier P, Pignata S, et al. Olaparib plus bevacizumab as first-line maintenance in ovarian cancer. *N Engl J Med.* 2019;381(25):2416-2428. **3.** Ray-Coquard I, Pautier P, Pignata S, et al. Olaparib plus bevacizumab as first-line maintenance in ovarian cancer. Supplementary Appendix. *N Engl J Med.* 2019;381(25):2416-2428. **4.** Konstantinopoulos PA, Ceccaldi R, Shapiro GI, D'Andrea AD. Homologous recombination deficiency: exploiting the fundamental vulnerability of ovarian cancer. *Cancer Discov.* 2015;5(11):1137-1154. **5.** Cancer Genome Atlas Research Network. Integrated genomic analyses of ovarian carcinoma. *Nature.* 2011;474(7353):609-615. **6.** Myriad MyChoice® CDx Technical Information. Myriad Genetic Laboratories, Inc. Accessed February 26, 2025. https://bit.ly/MyChoiceCDxSpecs **7.** U.S. Food & Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Accessed May 5, 2025. https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools **8.** Ray-Coquard I, Pautier P, Pignata S, et al. Olaparib plus bevacizumab as first-line maintenance in ovarian cancer. PAOLA-1 Protocol. *N Engl J Med.* 2019;381(25):2416-2428. **9.** Ray-Coquard I, Pautier P, Pignata S, et al. Phase III PAOLA-1/ENGOT-ov25: maintenance olaparib with bevacizumab in patients with newly diagnosed, advanced ovarian cancer treated with platinum-based chemotherapy and bevacizumab as standard of care. Poster presented at: ESMO 2019; September 27-October 1, 2019; Barcelona, Spain. **10.** FoundationOne®CDx Technical Information. Foundation Medicine, Inc. Accessed February 27, 2025. https://www.foundationmedicine.com/sites/default/files/media/documents/2025-01/F1cdx_technical_labeling_073124_clean_v27_RAL-0003.pdf **11.** Ray-Coquard I, Leary A, Pignata S, et al. Final overall survival results from the Phase III PAOLA-1/ENGOT-ov25 trial evaluating maintenance olaparib plus bevacizumab in patients with newly diagnosed advanced ovarian cancer. Presented at: ESMO Congress 2022; September 9-13, 2022; Paris, France. **12.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed February 26, 2025 **13.** Capoluongo E, Ellison G, López-Guerrero JA, et al. Guidance statement on *BRCA1/2* tumor testing in ovarian cancer patients. *Semin Oncol.* 2017;44(3):187-197. **14.** Myriad Genetics. MyChoice® CDx Myriad HRD Companion Diagnostic Test. Accessed February 26, 2025. https://myriad.com/genetic-tests/MyChoicecdx-tumor-test/ **15.** Heitz F, Ataseven B, Staniczok C, et al. Implementing HRD testing in routine clinical practice on patients with primary high-grade advanced ovarian cancer. *Cancers (Basel).* 2023;15(3):818. **16.** Ngoi NYL, Tan DSP. The role of homologous recombination deficiency testing in ovarian cancer and its clinical implications: do we need it? *ESMO Open.* 2021;6(3):100144.

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mPFS=median progression-free survival; NCCN=National Comprehensive Cancer Network® (NCCN®).

AstraZeneca

PAOLA-1 Study Design

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PAOLA-1 studied the efficacy and safety of LYNPARZA + bevacizumab vs an active comparator (bevacizumab + placebo)

- Advanced ovarian cancer following response to first-line platinum-based chemotherapy with bevacizumab. Bevacizumab was prescribed for at least 3 cycles in combination with platinum-based chemotherapy
- Patients were stratified by tumor *BRCA* mutation status and first-line treatment outcome. HRD status was not a stratification factor
- The ITT population was randomized 2:1 (N=806) to receive LYNPARZA tablets 300 mg orally BID in combination with bevacizumab 15 mg/kg infusion every 3 weeks (n=537) or placebo orally BID in combination with bevacizumab 15 mg/kg infusion every 3 weeks (n=269)
- Treatment with LYNPARZA was continued for up to 2 years or until disease progression or unacceptable toxicity. Patients with a partial response could continue treatment beyond 2 years at the physician's discretion. Bevacizumab was administered every 3 weeks for a total duration of up to 15 months, including the period given with chemotherapy and given as maintenance*
- The primary endpoint was the investigator-assessed PFS, and a key secondary endpoint was overall survival
  - **FDA approval for LYNPARZA + bevacizumab was based on a prespecified exploratory subgroup of patients with HRD-positive tumors (n=387)**

*Patients continued bevacizumab in the maintenance setting and started treatment with LYNPARZA after ≥3 weeks and ≤9 weeks following completion of their last dose of chemotherapy.

IMPORTANT SAFETY INFORMATION (Cont'd)

DRUG INTERACTIONS (Cont'd)

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

USE IN SPECIFIC POPULATIONS

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

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BID=twice daily.