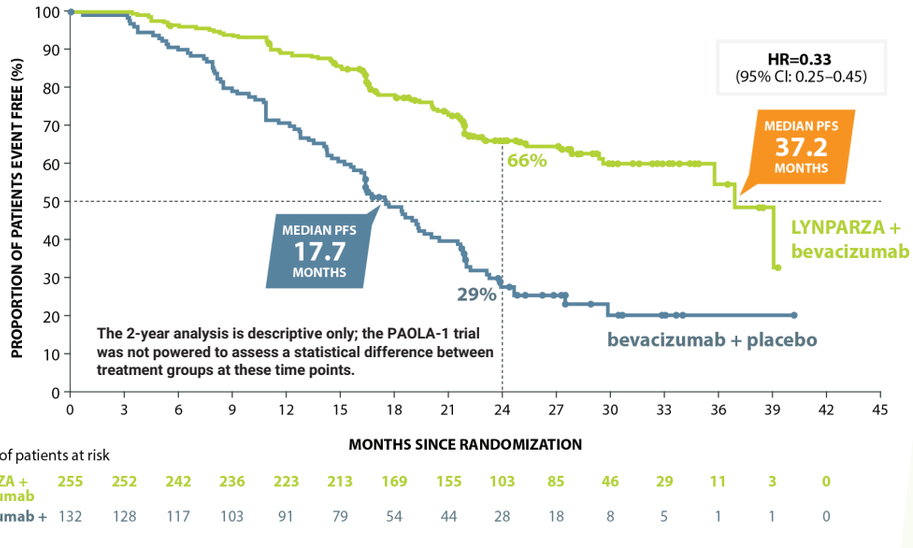
In women with HRD-positive advanced ovarian cancer, following complete or partial response to first-line platinum-based chemotherapy + bevacizumab[1]*

LYNPARZA® (olaparib) + bevacizumab demonstrated a clinically significant median PFS benefit of 3.1 years vs ~1.5 years with bevacizumab + placebo[1,2]

Lynparza® olaparib tablets 150 mg

PAOLA-1

HRD positive†
Prespecified exploratory analysis[2]



Number of patients at risk

LYNPARZA + bevacizumab	255	252	242	236	223	213	169	155	103	85	46	29	11	3	0
bevacizumab + placebo	132	128	117	103	91	79	54	44	28	18	8	5	1	1	0

Median PFS follow-up time: 27.4 months for LYNPARZA + bevacizumab and 27.5 months for bevacizumab + placebo[1]

~1 in 2 women with advanced ovarian cancer in PAOLA-1 was HRD positive[2]

(including *BRCA*m and genomic instability positive)[1]

PAOLA-1 Study Design[1-3]

PAOLA-1 was a phase 3 trial of women with advanced ovarian cancer that enrolled patients regardless of surgical outcome or *BRCA* mutation status following response to first-line platinum-based chemotherapy with bevacizumab. Patients were randomized 2:1 (N=806) to receive LYNPARZA tablets 300 mg BID in combination with bevacizumab 15 mg/kg (n=537) or placebo BID in combination with bevacizumab 15 mg/kg (n=269).

Bevacizumab was administered every 3 weeks for a total duration of up to 15 months, and LYNPARZA or placebo treatment was administered for up to 24 months or until disease progression or unacceptable toxicity.

The primary endpoint was the investigator-assessed PFS. Prespecified exploratory analyses included PFS in predefined subgroups, including HRD status and *BRCA* mutation status, **which were not controlled for Type 1 error. HRD status was not a stratification factor in PAOLA-1. PFS within HRD-positive patients served as the basis of the FDA-approved indication.**

*Select patients for this indication based on an FDA-approved companion diagnostic.[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.[4]

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.

SELECT SAFETY INFORMATION

LYNPARZA is associated with serious, potentially fatal risks, including myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) and pneumonitis. LYNPARZA can also cause fetal harm.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

Please see Important Safety Information throughout and accompanying complete Prescribing Information, including Patient Information (Medication Guide).

BID=twice daily; *BRCA*m=*BRCA*-mutated; CDx=companion diagnostic; CI=confidence interval; HR=hazard ratio; HRD=homologous recombination deficiency; PFS=progression-free survival; t*BRCA*=tumor *BRCA*.

In a post hoc exploratory subgroup analysis of PFS by clinical risk for relapse in HRD-positive patients[5]

Higher-risk patients mPFS: 3 years with LYNPARZA + bevacizumab and ~1.3 years with bevacizumab + placebo[5]

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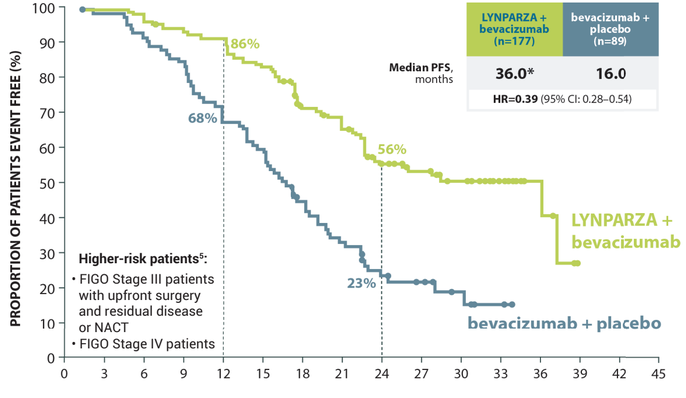

Median PFS, months	LYNPARZA + bevacizumab (n=177)	bevacizumab + placebo (n=89)
	36.0*	16.0

HR=0.39 (95% CI: 0.28–0.54)

Number of patients at risk

LYNPARZA + bevacizumab	177	175	166	161	150	140	109	95	63	50	27	15	5	0	0
bevacizumab + placebo	89	86	78	66	59	47	31	24	16	11	5	2	0	0	0

*Unstable median due to lack of events.[5]

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).

FIGO=International Federation of Gynecology and Obstetrics; mPFS=median progression-free survival; NACT=neoadjuvant chemotherapy; NR=not reached.

In a post hoc exploratory subgroup analysis of PFS by clinical risk for relapse in HRD-positive patients[5]

Lower-risk patients mPFS: NR with LYNPARZA + bevacizumab and ~1.8 years with bevacizumab + placebo[5]

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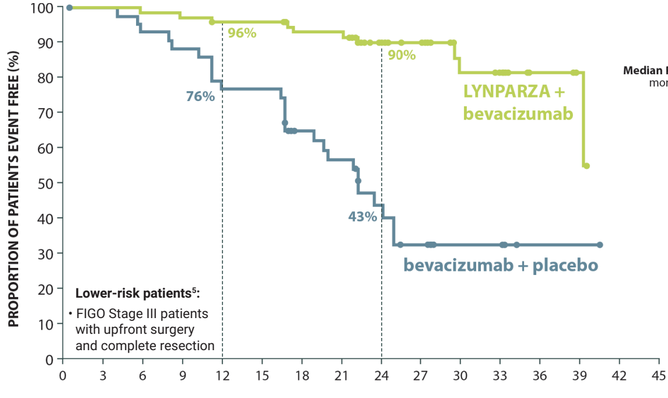

Median PFS, months	LYNPARZA + bevacizumab (n=78)	bevacizumab + placebo (n=43)
	NR	22.1

HR=0.15 (95% CI: 0.07–0.30)

Number of patients at risk

LYNPARZA + bevacizumab	78	77	76	75	73	73	60	60	40	35	19	14	6	3	0
bevacizumab + placebo	43	42	39	37	32	32	23	20	12	7	3	3	1	1	0

There is no official clinical consensus on what is considered higher vs lower risk. Data are based on post hoc exploratory subgroup analyses in 2 clinical subgroups (higher risk and lower risk), including by biomarker status. Neither HRD status nor risk factor was a stratification factor in PAOLA-1.[2,3]

*Unstable median due to lack of events.[5]

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 count weekly until recovery.

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).

FIGO=International Federation of Gynecology and Obstetrics; mPFS=median progression-free survival; NACT=neoadjuvant chemotherapy; NR=not reached.

Adverse reactions and laboratory abnormalities in PAOLA-1[1]

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ARs occurring in ≥10% of patients treated with LYNPARZA + bevacizumab and at ≥5% frequency compared with placebo + bevacizumab[1]

LYNPARZA + bevacizumab (n=535)

bevacizumab + placebo (n=267)

Adverse reactions*	Grades 1–4 (%)	Grades 3–4 (%)
Fatigue (including asthenia)†	53 32	5 1.5
Nausea	53 22	2.4 0.7
Vomiting	22 11	1.7 1.9
Anemia‡	41 10	17 0.4
Lymphopenia§	24 9	7 1.1
Leukopenia‖	18 10	1.9 1.5

*Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0. †Includes asthenia and fatigue. ‡Includes anemia, anemia macrocytic, erythropenia, hematocrit decreased, hemoglobin decreased, normochromic anemia, normochromic normocytic anemia, normocytic anemia, and red blood cell count decreased. §Includes B-lymphocyte count decreased, lymphocyte count decreased, lymphopenia, and T-lymphocyte count decreased. ‖Includes leukopenia and white blood cell count decreased.

In addition, venous thromboembolic events occurred more commonly in patients receiving LYNPARZA + bevacizumab (5%) than in those receiving placebo + bevacizumab (1.9%)[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%).[1]

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).

AR=adverse reaction.

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Lab abnormalities reported in ≥25% of women on LYNPARZA + bevacizumab vs bevacizumab + placebo[1¶]

LYNPARZA + bevacizumab (n=535)#

bevacizumab + placebo (n=267)#

Laboratory parameter**	Grades 1–4 (%)	Grades 3–4 (%)
Decrease in hemoglobin	79 55	13 0.4
Decrease in lymphocytes	63 42	10 3
Increase in serum creatinine	61 36	0.4 0.4
Decrease in leukocytes	59 45	3.4 2.2
Decrease in absolute neutrophil count	35 30	7 3.7
Decrease in platelets	35 28	2.4 0.4

¶Reported within 30 days of the last dose. #This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter. **Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.

ARs and laboratory abnormalities in PAOLA-1 were mostly Grades 1 and 2[1]

In patients receiving LYNPARZA + bevacizumab, dose interruptions of LYNPARZA due to an adverse reaction of any grade occurred in 54% of patients, dose reductions of LYNPARZA due to an adverse reaction occurred in 41% of patients, and discontinuation of LYNPARZA due to adverse reactions occurred in 20% of patients.[1]

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).

AR=adverse reaction.

In women with sBRCAm or gBRCAm* advanced ovarian cancer following response to first-line platinum-based chemotherapy*[1,6]*

Primary analysis: mPFS not reached with LYNPARZA® (olaparib) vs ~1.2 years with placebo[1,6]

SOLO-1

sBRCAm or gBRCAm[1,6]

Median PFS[1,6]

LYNPARZA	Placebo
not reached (NR)	13.8 months

HR=0.30; 95% CI: 0.23–0.41; *P*<0.0001

Median duration of follow-up (primary analysis): 41 months for LYNPARZA and 41 months for placebo (DCO: May 17, 2018).[1,6]

22% of women with ovarian cancer have a *BRCA* mutation[7,8]

- 15% g*BRCA*m[7†]
- 7% s*BRCA*m[8‡]

SOLO-1 Study Design[1,6]

SOLO-1 was a phase 3 trial of women with s*BRCA*m or g*BRCA*m advanced ovarian cancer in complete or partial response to first-line platinum-based chemotherapy. Patients were randomized 2:1 (N=391) to receive LYNPARZA tablets 300 mg BID (n=260) or placebo (n=131). The primary endpoint was investigator-assessed PFS.

Treatment with LYNPARZA was continued for up to 2 years or until disease progression or unacceptable toxicity. Patients who remained in CR received a maximum treatment duration of 2 years; patients whose disease remained stable could continue to receive LYNPARZA beyond 2 years.

*Select patients for this indication based on an FDA-approved companion diagnostic.[1]
†Based on a 2005 population-based study of 209 women with invasive ovarian carcinoma who underwent genetic testing through full sequencing and *BRCA1* rearrangement.[7]
‡Based on a 2014 study of 390 ovarian carcinomas, with prospective enrollment at diagnosis, using targeted capture and massively parallel genomic sequencing.[8]

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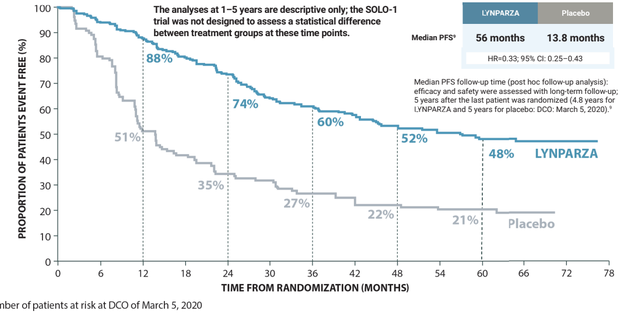
Post hoc 5-year follow-up analysis: mPFS was ~4.7 years with LYNPARZA® (olaparib) and ~1.2 years with placebo[9]



	LYNPARZA	Placebo
Median PFS*	56 months	13.8 months

HR=0.33; 95% CI: 0.25–0.43

Median PFS follow-up time (post hoc follow-up analysis): efficacy and safety were assessed with long-term follow-up; 5 years after the last patient was randomized (4.8 years for LYNPARZA and 5 years for placebo: DCO: March 5, 2020).[9]

Number of patients at risk at DCO of March 5, 2020

LYNPARZA	260	229	212	194	173	140	129	115	101	91	58	30	2	0
Placebo	131	103	65	53	41	38	30	24	23	22	16	3	0	0

INDICATION

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

First-Line Maintenance *BRCA*m Advanced Ovarian Cancer
For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).
AR=adverse reaction; CR=complete response; DCO=data cutoff; g*BRCA*m=germline *BRCA*-mutated; s*BRCA*m=somatic *BRCA*-mutated.

Adverse reactions and laboratory abnormalities in SOLO-1[1]

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ARs reported in ≥10% of women on LYNPARZA vs placebo[1]

Adverse reactions*	LYNPARZA (n=260) Grades 1–4 (%)	Placebo (n=130) Grades 1–4 (%)	LYNPARZA (n=260) Grades 3–4 (%)	Placebo (n=130) Grades 3–4 (%)
Fatigue†	67	42	4	2
Anemia	38	9	21	2
Neutropenia‡	17	7	6	3
Leukopenia§	13	8	3	0
Thrombocytopenia‖	11	4	1	2
Nausea	77	38	1	0
Vomiting	40	15	0	1
Abdominal pain¶	45	35	2	1
Diarrhea#	37	26	3	0
Dyspepsia	17	12	0	0
Constipation	28	19	0	0
Stomatitis**	11	2	0	0
Upper respiratory tract infection/influenza/ nasopharyngitis/bronchitis	28	23	0	0
UTI††	13	7	1	0
Decreased appetite	20	10	0	0
Dyspnea‡‡	15	6	0	0
Dysgeusia	26	4	0	0
Dizziness	20	15	0	1

At 5-year follow-up analysis

- **No additional cases of MDS/AML reported; incidence remained <1.5%. Follow-up for MDS/AML continued until death due to any cause**[9]
- **Safety profile remained consistent with the primary analysis**[9]

*Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0. †Includes asthenia, fatigue, lethargy, malaise. ‡Includes neutropenia, febrile neutropenia. §Includes leukopenia, white blood cell count decreased. ‖Includes platelet count decreased, thrombocytopenia. ¶Includes abdominal pain, abdominal pain lower, abdominal pain upper, abdominal distension, abdominal discomfort, abdominal tenderness. #Includes colitis, diarrhea, gastroenteritis. **Includes stomatitis, aphthous ulcer, mouth ulceration. ††Includes urosepsis, UTI, urinary tract pain, pyuria. ‡‡Includes dyspnea and dyspnea exertional.

Lab abnormalities reported in ≥25% of women on LYNPARZA vs placebo[1]

Laboratory parameter‖‖	LYNPARZA (n=260)[§§] Grades 1–4 (%)	Placebo (n=130)[§§] Grades 1–4 (%)	LYNPARZA (n=260)[§§] Grades 3–4 (%)	Placebo (n=130)[§§] Grades 3–4 (%)
Decrease in hemoglobin	87	63	19	2
Increase in mean corpuscular volume	87	43	0	0
Decrease in leukocytes	70	52	7	1
Decrease in lymphocytes	67	29	14	5
Decrease in absolute neutrophil count	51	38	9	6
Increase in serum creatinine	34	18	0	0
Decrease in platelets	35	20	1	2

[§§]This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter. ‖‖Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.

Monitor patients for hematological toxicity at baseline and monthly thereafter.

Among patients who received LYNPARZA, dose interruptions due to an adverse reaction of any grade occurred in 52%, and dose reductions due to an adverse reaction occurred in 28%. Discontinuation due to adverse reactions occurred in 12% of patients receiving LYNPARZA.[1]

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).
AML=acute myeloid leukemia; MDS=myelodysplastic syndrome; UTI=urinary tract infection.

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

LYNPARZA® (olaparib) + bevacizumab demonstrated a clinically significant median PFS benefit of 3.1 years vs ~1.5 years with bevacizumab + placebo.

HR=0.33 (95% CI: 0.25–0.45)[1]

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

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Pneumonitis: Occurred in 0.8% of patients exposed to LYNPARZA monotherapy, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. A pregnancy test is recommended for 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.

ADVERSE REACTIONS—First-Line Maintenance *BRCA*m Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients in clinical trials of LYNPARZA in the **first-line maintenance setting** for **SOLO-1** were: nausea (77%), fatigue (67%), abdominal pain (45%), vomiting (40%), anemia (38%), diarrhea (37%), constipation (28%), upper respiratory tract infection/influenza/nasopharyngitis/bronchitis (28%), dysgeusia (26%), decreased appetite (20%), dizziness (20%), neutropenia (17%), dyspepsia (17%), dyspnea (15%), leukopenia (13%), UTI (13%), thrombocytopenia (11%), and stomatitis (11%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients in clinical trials of LYNPARZA in the **first-line maintenance setting** for **SOLO-1** were: decrease in hemoglobin (87%), increase in mean corpuscular volume (87%), decrease in leukocytes (70%), decrease in lymphocytes (67%), decrease in absolute neutrophil count (51%), decrease in platelets (35%), and increase in serum creatinine (34%).

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 compared to a ≥5% frequency for 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%).

ADVERSE REACTIONS—First-Line Maintenance Advanced Ovarian Cancer in Combination with Bevacizumab (Cont'd)

In addition, venous thromboembolic events 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.

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).

Please see accompanying complete Prescribing Information, including Patient Information (Medication Guide).

You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. **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.** 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. **5.** Harter P, et al. Efficacy of maintenance olaparib plus bevacizumab by biomarker status in clinical higher- and lower-risk patients with newly diagnosed, advanced ovarian cancer in the PAOLA-1/ENGOT-ov25 trial. Abstract presented at: IGCS Annual Global Meetings; September 10-13, 2020; virtual meeting. **6.** Moore K, Colombo N, Scambia G, et al. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer. *N Engl J Med*. 2018;379(26):2495-2505. **7.** Pal T, Permuth-Wey J, Betts JA, et al. *BRCA1* and *BRCA2* mutations account for a large proportion of ovarian carcinoma cases. *Cancer*. 2005;104(12):2807-2816. **8.** Pennington KP, Walsh T, Harrell MI, et al. Germline and somatic mutations in homologous recombination genes predict platinum response and survival in ovarian, fallopian tube, and peritoneal carcinomas. *Clin Cancer Res*. 2014;20(3):764-775. **9.** Banerjee S, Moore K, Colombo N, et al. Maintenance olaparib for patients with newly diagnosed advanced ovarian cancer and a *BRCA* mutation: 5-year follow-up from SOLO1. Presented at the ESMO Virtual Congress 2020; September 19-21, 2020.

AstraZeneca