Lynparza®
olaparib
tablets 150 mg

The first and only PARPi FDA approved in **2 distinct breast cancer treatment settings**[1-4]

See Indications below.

Not actual patients.

Discover more about targeted treatment with LYNPARZA for eligible patients with gBRCAm, HER2-negative early or metastatic breast cancer[1]

INDICATIONS

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

Adjuvant Treatment of g*BRCA*m, HER2-Negative, High-Risk Early Breast Cancer

For the adjuvant treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

g*BRCA*m, HER2-Negative Metastatic Breast Cancer

For the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. 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 with various *BRCA*m, g*BRCA*m, HRR gene-mutated or HRD-positive cancers who received LYNPARZA 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.

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.

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

g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HER2=human epidermal growth factor receptor 2; HRD=homologous recombination deficiency; HRR=homologous recombination repair; PARPi=poly (ADP-ribose) polymerase inhibitor.

OlympiA was designed to evaluate LYNPARZA as adjuvant therapy in certain patients with gBRCAm,* HER2-negative, high-risk early breast cancer[1]

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OlympiA was a phase 3, randomized, double-blind, placebo-controlled, international clinical trial[1,5]

SCREENING
- g*BRCA* mutation
- HER2-negative (HR-positive or TNBC)
- Early breast cancer (eBC)

HIGH-RISK INCLUSION CRITERIA

NEOADJUVANT CHEMOTHERAPY† → **SURGERY‡**

HR-positive: non-pCR with CPS&EG ≥3
TNBC: non-pCR

OR

SURGERY → **ADJUVANT CHEMOTHERAPY†‡**

HR-positive: ≥4 positive lymph nodes
TNBC: ≥pN1 or pN0 with ≥pT2

Patient baseline characteristics ⊕ CPS&EG score ⊕

1:1 Randomization

N=1836

LYNPARZA 300 mg BID (n=921) and endocrine therapy per current clinical practice guidelines for patients with HR-positive tumors

Placebo BID (n=915) and endocrine therapy per current clinical practice guidelines for patients with HR-positive tumors

LYNPARZA or placebo was given for up to 12 months, or until disease recurrence or unacceptable toxicity

STRATIFICATION FACTORS
- HR-positive vs TNBC
- Prior neoadjuvant vs adjuvant chemotherapy
- Prior platinum-based chemotherapy (yes vs no)

PRIMARY ENDPOINT
- Invasive disease-free survival (IDFS)

KEY SECONDARY ENDPOINTS
- Overall survival (OS)§
- Distant disease-free survival (DDFS)§
- Safety

OlympiA protocol included both patients with HR-positive disease and TNBC.[1,5]
- Patients with TNBC were included at protocol activation in 2014
- Protocol amended in 2015 to include patients with HR-positive disease. Enrollment began in December 2015

The CPS&EG scoring system estimates relapse probability on the basis of pre-treatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade.[1,5]

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

†At least 6 cycles of neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes, or both agents. Platinum-based chemotherapy was allowed.[1]

‡Radiation therapy was given when appropriate.[5]

§OS and DDFS were controlled for Type 1 error within a hierarchical statistical analysis in OlympiA.[6]

BID=twice daily; CI=confidence interval; CPS&EG=pre-treatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HER2=human epidermal growth factor receptor 2; HR=hormone receptor; TNBC=triple-negative breast cancer.

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.

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.

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.

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

Targeted treatment with LYNPARZA for eligible patients with gBRCAm, HER2-negative, high-risk eBC

Significantly improved IDFS benefit vs placebo in OlympiA*[1,5]

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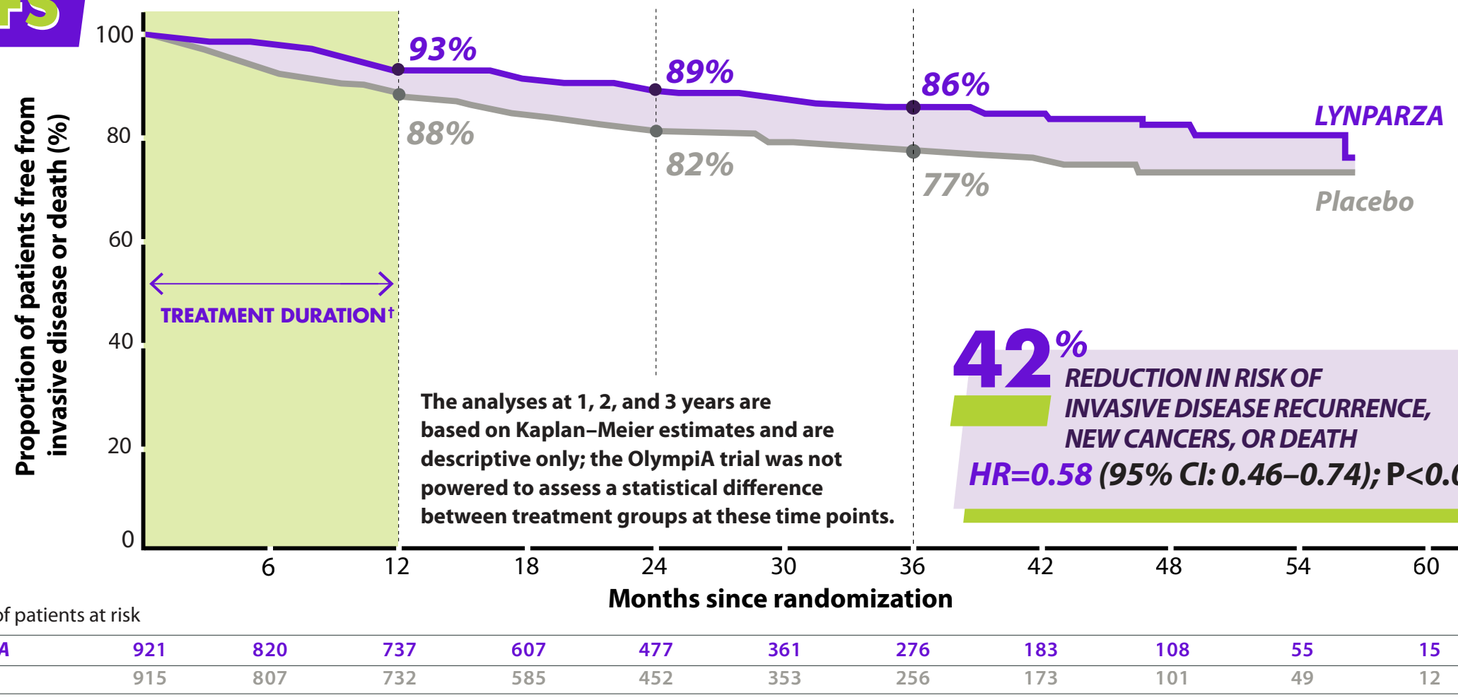
PRIMARY ENDPOINT

IDFS



The analyses at 1, 2, and 3 years are based on Kaplan–Meier estimates and are descriptive only; the OlympiA trial was not powered to assess a statistical difference between treatment groups at these time points.

42% ***REDUCTION IN RISK OF INVASIVE DISEASE RECURRENCE, NEW CANCERS, OR DEATH***

HR=0.58 (95% CI: 0.46–0.74); P<0.0001

Number of patients at risk

LYNPARZA	921	820	737	607	477	361	276	183	108	55	15
Placebo	915	807	732	585	452	353	256	173	101	49	12

- The threshold of statistical significance was 0.005[1]
- The number of IDFS events observed was 106 with LYNPARZA (n=921) vs 178 with placebo (n=915)[1]
- Data from the pre-specified interim analysis (86% of the number of events for the planned final analysis)[1]

*Invasive disease-free survival was defined as the time to first invasive breast cancer recurrence (loco-regional or distant), second primary cancer, or death from any cause.[1]

†LYNPARZA was administered for up to 12 months or until disease recurrence or unacceptable toxicity.[1]

CI=confidence interval; eBC=early breast cancer; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HR=hazard ratio; IDFS=invasive disease-free survival.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

Embryo-Fetal Toxicity (Cont´d)

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.

Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

ADVERSE REACTIONS—Adjuvant Treatment of g*BRCA*m, HER2-Negative, High-Risk Early Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: nausea (57%), fatigue (including asthenia) (42%), anemia (24%), vomiting (23%), headache (20%), diarrhea (18%), leukopenia (17%), neutropenia (16%), decreased appetite (13%), dysgeusia (12%), dizziness (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: decrease in lymphocytes (77%), increase in mean corpuscular volume (67%), decrease in hemoglobin (65%), decrease in leukocytes (64%), and decrease in absolute neutrophil count (39%).

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

Targeted treatment with LYNPARZA for eligible patients with gBRCAm, HER2-negative, high-risk eBC

Significantly improved OS vs placebo in OlympiA[1,7]

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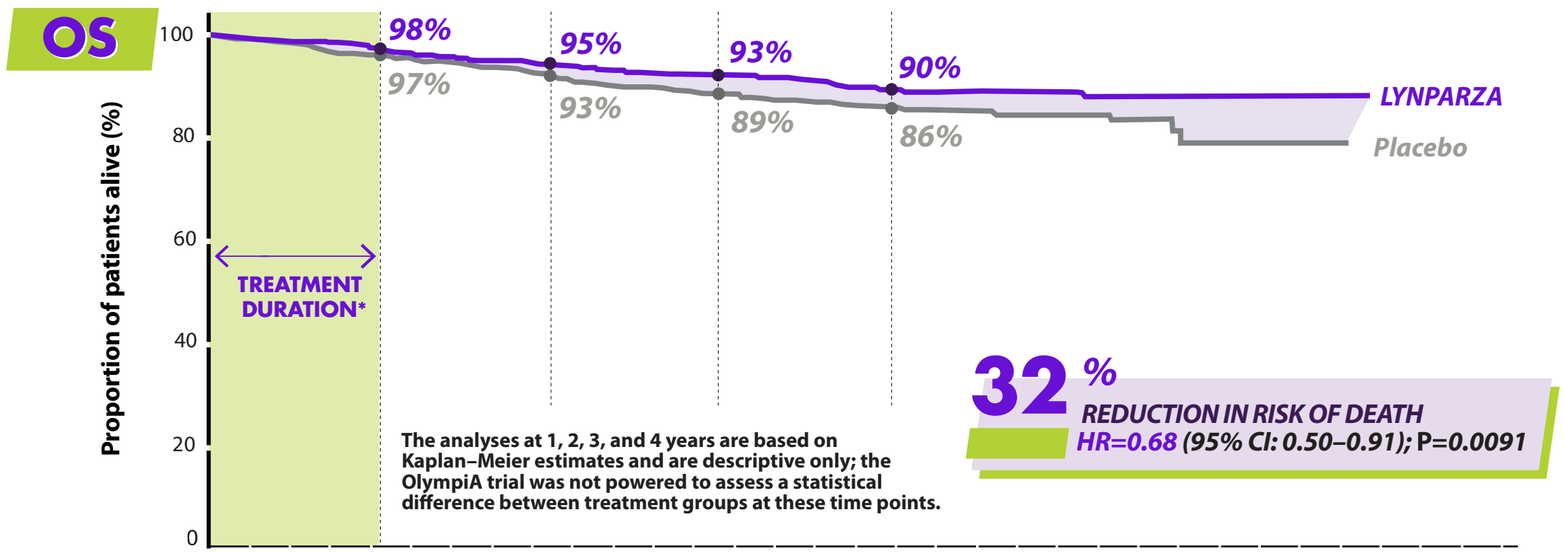
KEY SECONDARY ENDPOINT



The analyses at 1, 2, 3, and 4 years are based on Kaplan–Meier estimates and are descriptive only; the OlympiA trial was not powered to assess a statistical difference between treatment groups at these time points.

32% ***REDUCTION IN RISK OF DEATH***
HR=0.68 (95% CI: 0.50–0.91); P=0.0091

Number of patients at risk

LYNPARZA	921	862	844	809	773	672	560	437	355	228	151	70	16	6	0	0
Placebo	915	868	843	808	752	647	530	423	333	218	141	74	17	4	0	0

- OS was controlled for Type 1 error within a hierarchical statistical analysis in OlympiA[6]
- The threshold of statistical significance was 0.015[1]
- The number of deaths was 75 with LYNPARZA (n=921) vs 109 with placebo (n=915)[1]
- Data from the pre-specified second interim analysis of OS (at ~330 IDFS events)[1]

Adjuvant treatment with LYNPARZA may give your eligible patients the opportunity to live longer[1]

*LYNPARZA was administered for up to 12 months or until disease recurrence or unacceptable toxicity.[1]

eBC=early breast cancer; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HR=hazard ratio; IDFS=invasive disease-free survival; OS=overall survival.

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—g*BRCA*m, HER2-Negative Metastatic Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: decrease in hemoglobin (82%), decrease in lymphocytes (73%), decrease in leukocytes (71%), increase in mean corpuscular volume (71%), decrease in absolute neutrophil count (46%), and decrease in platelets (33%).

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.

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

Select adverse reactions (ARs) in OlympiA

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ARs in OlympiA (≥10% of patients who received LYNPARZA)[1]

LYNPARZA (n=911) Placebo (n=904)

Adverse reactions*	Grades 1–4 (%)	Grades 3–4 (%)
Nausea	57 23	0.8 0
Vomiting	23 8	0.7 0
Diarrhea	18 14	0.3 0.3
Stomatitis†	10 4.5	0.1 0
Fatigue (including asthenia)	42 28	1.8 0.7
Anemia‡	24 3.9	9 0.3
Leukopenia§	17 6	3 0.3
Neutropenia‖	16 7	5 0.8
Headache	20 17	0.2 0.1
Dysgeusia¶	12 4.8	0 0
Dizziness	11 7	0.1 0.1
Decreased appetite	13 6	0.2 0

ARs in OlympiA were mostly Grades 1 and 2[1]

*Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.

†Includes aphthous ulcer, mouth ulceration, stomatitis.

‡Includes anemia, anemia macrocytic, erythropenia, hematocrit decreased, hemoglobin decreased, normochromic anemia, normochromic normocytic anemia, normocytic anemia, red blood cell count decreased.

§Includes leukopenia, white blood cell count decreased.

‖Includes agranulocytosis, febrile neutropenia, granulocyte count decreased, granulocytopenia, idiopathic neutropenia, neutropenia, neutropenic infection, neutropenic sepsis, neutrophil count decreased.

¶Includes dysgeusia, taste disorder.

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

Select laboratory abnormalities in OlympiA

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Laboratory abnormalities reported in ≥25% of patients in OlympiA[1]

LYNPARZA (n=911)* Placebo (n=904)*

Laboratory parameter†	Grades 1–4 (%)	Grades 3–4 (%)
Decrease in lymphocytes	77 59	13 3.7
Increase in mean corpuscular volume‡	67 4.8	0 0
Decrease in hemoglobin	65 31	8 0.9
Decrease in leukocytes	64 42	5 0.7
Decrease in absolute neutrophil count	39 27	7 1.1

*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.

‡Represents the proportion of subjects whose mean corpuscular volume was >ULN.

CTCAE=Common Terminology Criteria for Adverse Events; ULN=upper limit of normal.

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

Dose modifications due to ARs in OlympiA[1]

	LYNPARZA (n=911)
Dose interruptions due to ARs	31%
Dose reductions due to ARs	23%
Discontinuations due to ARs	10%

- The most common ARs leading to dose interruptions were anemia (11%), neutropenia (6%), nausea (5%), leukopenia (3.5%), fatigue (3%), and vomiting (2.9%)[1]
- The most common ARs leading to dose reductions were anemia (8%), nausea (4.7%), neutropenia (4.2%), fatigue (3.3%), leukopenia (1.8%), and vomiting (1.5%)[1]
- The most common ARs leading to discontinuation were nausea (2%), anemia (1.8%), and fatigue (1.3%)[1]

~9 out of 10 patients continued treatment with LYNPARZA without AR-related discontinuation[1]

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

OlympiAD was designed to evaluate LYNPARZA in certain patients with gBRCAm, HER2-negative metastatic breast cancer[1]

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OlympiAD was a phase 3, open-label, randomized, controlled, multicenter study[1,8]

SCREENING

- *gBRCAm mBC*
- *TNBC or HR-positive, HER2-negative*

REQUIRED PRIOR THERAPY

All patients (N=302) *in the neoadjuvant, adjuvant, or metastatic setting:*

- *anthracycline (unless contraindicated)*
- *a taxane*
- *≤2 lines of prior chemotherapy for mBC*

HR-positive disease

- *Progression on at least 1 endocrine therapy (adjuvant or metastatic), or deemed inappropriate for endocrine therapy by treating physician*

If prior platinum-based chemotherapy

- *In metastatic disease: No evidence of disease progression during platinum-based treatment*
- *In the adjuvant or neoadjuvant setting: ≥12 months since last dose*

STRATIFICATION FACTORS

- Prior chemotherapy regimens for mBC
- HR status
- Prior platinum-based chemotherapy

Patient baseline characteristics ⊕ **Patient eligibility** ⊕

2:1
Randomization
N=302

- **LYNPARZA** tablets 300 mg orally BID (n=205)
- Physician's choice of **chemotherapy*** (n=97)

Treatment continued until disease progression or unacceptable toxicity.

PRIMARY ENDPOINT

- Progression-free survival (BICR-assessed per RECIST v1.1)

SELECT PRESPECIFIED SECONDARY ENDPOINTS, INITIAL ANALYSES

- ORR in patients with measurable disease (BICR-assessed)
- Overall survival

- Approximately 29% of patients received LYNPARZA as their first treatment for mBC[1,3]
- Approximately 71% of patients received LYNPARZA as their second or later treatment for mBC[1,8]

*Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]

BICR=blinded independent central review; BID=twice daily; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HR=hazard ratio or hormone receptor; mBC=metastatic breast cancer; ORR=objective response rate; RECIST=Response Evaluation Criteria in Solid Tumors; TNBC=triple-negative breast cancer.

IMPORTANT SAFETY INFORMATION (Cont'd)

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

Significantly improved PFS vs physician's choice of chemotherapy in OlympiAD[1,8]

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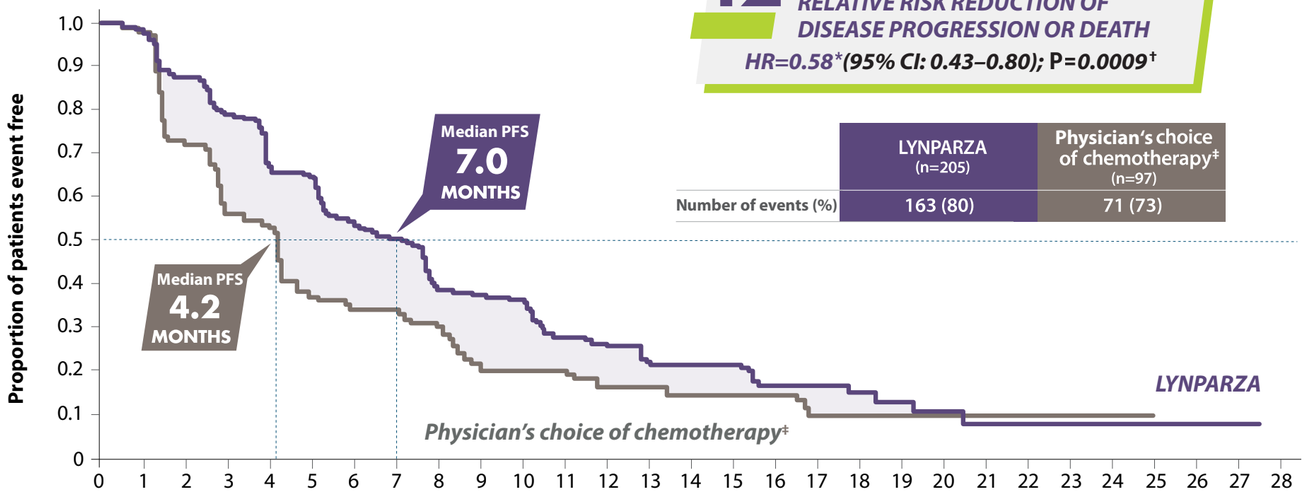
Primary endpoint: progression-free survival (PFS)[1,8]



42% *RELATIVE RISK REDUCTION OF DISEASE PROGRESSION OR DEATH*

HR=0.58(95% CI: 0.43–0.80); P=0.0009†*

	LYNPARZA (n=205)	Physician's choice of chemotherapy‡ (n=97)
Number of events (%)	163 (80)	71 (73)

Number of patients at risk

LYNPARZA	205	201	177	159	154	129	107	100	94	73	69	61	40	36	23	21	21	11	11	11	4	3	3	2	2	1	1	1	0
Physician's choice of chemotherapy‡	97	88	63	46	44	29	25	24	21	13	11	11	8	7	4	4	4	1	1	1	1	1	1	1	1	0	0	0	0

PFS at 12 months[8]

- 25.9% of patients treated with LYNPARZA and 15.0% of patients treated with chemotherapy‡

The analysis at 12 months is based on Kaplan-Meier estimates and is descriptive only; the OlympiAD trial was not designed to assess a statistical difference between treatment groups at this time point.[5]

*Hazard ratio is derived from a stratified log-rank test, stratified by ER, PgR-negative vs ER and/or PgR-positive and prior chemotherapy (yes vs no).[1]

†For PFS, *P* value (2-sided) was compared with 0.05.[1]

‡Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]

ER=estrogen receptor; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); HR=hazard ratio or hormone receptor; mBC=metastatic breast cancer; PgR=progesterone receptor.

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 with various *BRCA*m, g*BRCA*m, HRR gene-mutated or HRD-positive cancers who received LYNPARZA 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.

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.

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

ORR and OS results in OlympiAD[1]

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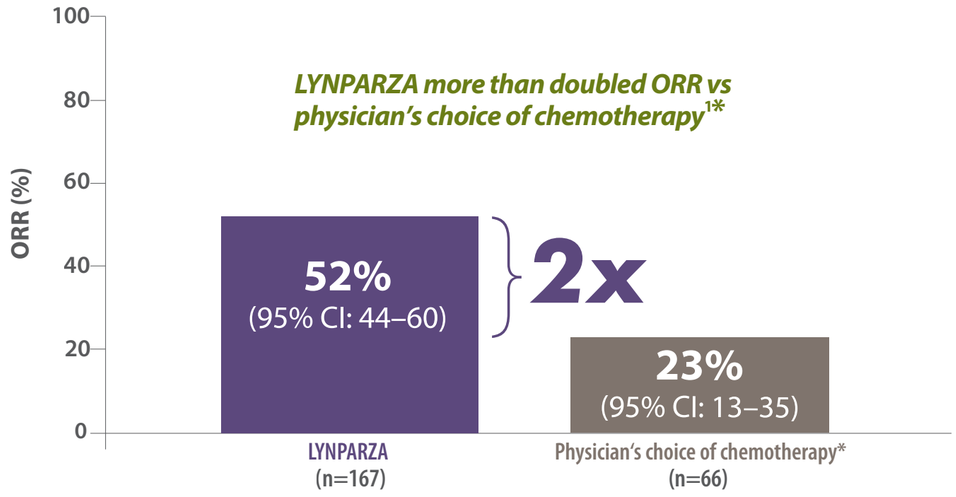
Prespecified secondary endpoint, initial analysis: objective response rate (ORR) in patients with measurable disease (BICR-assessed)[1]



ORR was a prespecified secondary endpoint. The OlympiAD trial was not powered to assess statistical difference in ORR or median duration of response between treatment groups.[8]

- The confirmed complete response rate was 7.8% for LYNPARZA and 1.5% for the chemotherapy arm[1]*
- The median duration of response was 6.4 months for LYNPARZA and 7.1 months for the chemotherapy arm[8]*

Time of data cutoff for the initial analysis was December 9, 2016[8]

Response based on confirmed responses.[1]
ORR=CR+PR based on BICR, according to modified RECIST, version 1.1.[8]

A follow-up analysis for duration of response (DOR) was conducted among patients who demonstrated an objective response. This analysis was exploratory and was not a randomized comparison. Results should be interpreted with caution.[9]

- Investigator-assessed ORR was recorded in 95 patients (57.6%) in the LYNPARZA arm (n=165) and 16 patients (22.2%) in the chemotherapy arm (n=72)[9]*
- Among responders, the median DOR was 6.9 months in the LYNPARZA arm and 4.5 months in the chemotherapy arm[9]*
- Time of data cutoff for the follow-up analysis was September 25, 2017, representing an approximately 9-month extension from the time of data cutoff for the initial analysis[9]

Median DoR is based on the final analysis using investigator-assessed ORR.[9]

*Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]
CR=complete response; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); mBC=metastatic breast cancer; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors.

Prespecified secondary endpoint: overall survival

Median OS in the total study population was 19.3 months with LYNPARZA and 17.1 months with physician's choice of chemotherapy. HR=0.90 (95% CI: 0.66–1.23). OS did not achieve statistical significance. OlympiAD was not powered to show statistical significance in OS for LYNPARZA monotherapy vs chemotherapy.[5,9]

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.

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.

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.

Males
Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

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

Select adverse reactions (ARs) in OlympiAD[1]

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ARs* in OlympiAD (≥20% of patients who received LYNPARZA)[1]

LYNPARZA (n=205)* | Physician's choice of chemotherapy (n=91)†‡

Adverse reactions	Grades 1–4 (%)	Grades 3–4 (%)
Anemia[§]	40 26	16 4
Leukopenia[‖]	25 31	5 13
Neutropenia[¶]	27 50	9 26
Nausea	58 35	0 1
Vomiting	30 15	0 1
Diarrhea	21 22	1 0
Respiratory tract infection[#]	27 22	1 0
Fatigue (including asthenia)	37 36	4 1
Headache	20 15	1 2

ARs in OlympiAD were mostly Grades 1 and 2[1]

*Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.

† 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.

‡Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]

§Represents grouped terms consisting of anemia (anemia erythropenia, hematocrit decreased, hemoglobin decreased, and red blood cell count decreased).

‖Represents grouped terms consisting of leukopenia and white blood cell count decreased.

¶Represents grouped terms consisting of neutropenia (febrile neutropenia, granulocyte count decreased, granulocytopenia, neutropenia, neutropenic infection, neutropenic sepsis, and neutrophil count decreased).

#Represents grouped terms consisting of bronchitis, influenza, lower respiratory tract infection, nasopharyngitis, respiratory tract infection, rhinitis, sinusitis, upper respiratory tract infection, and upper respiratory tract infection bacterial.

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

Select laboratory abnormalities in OlympiAD

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Laboratory abnormalities reported in ≥25% of patients in OlympiAD[1]

LYNPARZA (n=205)* | Physician's choice of chemotherapy† (n=91)*

Laboratory parameter‡	Grades 1–4 (%)	Grades 3–4 (%)
Increase in mean corpuscular volume§	71 33	0 0
Decrease in hemoglobin	82 66	17 3
Decrease in leukocytes	71 70	8 23
Decrease in lymphocytes	73 63	21 3
Decrease in absolute neutrophil count	46 65	11 38
Decrease in platelets	33 28	3 0

*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.

†Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]

‡Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.

§Represents the proportion of subjects whose mean corpuscular volume was >ULN.

ULN=upper limit of normal.

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

Dose modifications due to ARs in OlympiAD[1,8]

	LYNPARZA (n=205)	Physician's choice of chemotherapy* (n=91)
Dose interruptions due to ARs	35%	28%
Dose reductions due to ARs	25%	31%
Discontinuations due to ARs	5%	8%

- Discontinuation rates associated with hematologic ARs in patients receiving LYNPARZA were anemia (2%), decreased platelet count (1%), thrombocytopenia (0.5%), neutropenia (0%), and leukopenia (0%)[10,11]

~9 out of 10 patients continued treatment with LYNPARZA without AR-related discontinuation[1]

*Physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine).[1,8]

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

TEST ▸ TARGET ▸ TREAT
Consider LYNPARZA for your eligible patients with gBRCAm, HER2-negative breast cancer in the adjuvant or metastatic setting[1]

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In high-risk* patients in the adjuvant setting

OlympiA

Not an actual patient.

Primary Endpoint: Statistically Significant IDFS

42% REDUCTION IN RISK OF INVASIVE DISEASE recurrence, new cancers, or death vs placebo

HR=0.58 (95% CI: 0.46–0.74); P<0.0001[1]

Key Secondary Endpoint: Statistically Significant OS

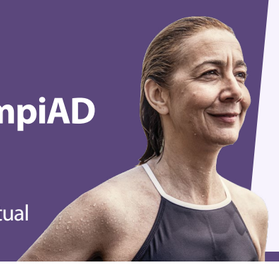
32% REDUCTION IN RISK OF DEATH vs placebo

HR=0.68 (95% CI: 0.50–0.91); P=0.0091[1]

The most common ARs (Grades 1–4) in ≥10% of patients were: nausea (57%), fatigue (including asthenia) (42%), anemia (24%), vomiting (23%), headache (20%), diarrhea (18%), leukopenia (17%), neutropenia (16%), decreased appetite (13%), dysgeusia (12%), dizziness (11%), and stomatitis (10%).

In the metastatic setting

OlympiAD



Not an actual patient.

Primary Endpoint: Statistically Significant PFS

42% RELATIVE RISK REDUCTION OF DISEASE PROGRESSION OR DEATH VS CHEMOTHERAPY

HR=0.58 (95% CI: 0.43–0.80); P=0.0009[1,8]

Median PFS was 7.0 months with LYNPARZA and 4.2 months for physician's choice of chemotherapy

Prespecified Secondary Endpoints: ORR† and OS

ORR†: 52% WITH LYNPARZA (N=167) and 23% with physician's choice of chemotherapy (n=66)

OS: HR=0.90 (95% CI: 0.66–1.23)[1,8]

Median OS was 19.3 months with LYNPARZA and 17.1 months in the chemotherapy arm. OS did not reach statistical significance

The most common ARs (Grades 1–4) in ≥20% of patients were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

*For patients who received prior neoadjuvant chemotherapy, high risk was defined as non-pCR in TNBC and as non-pCR with CPS&EG score ≥3 in HR-positive, HER2-negative disease. For patients who received prior adjuvant chemotherapy, high risk was defined as ≥pN1 or pN0 with ≥pT2 in TNBC and as ≥4 positive lymph nodes in HR-positive, HER2-negative disease.[1]

†In patients with measurable disease. Response based on confirmed responses. ORR=CR+PR based on BICR, according to modified RECIST, version 1.1.[1]

OlympiAD was not powered to assess a statistical difference in ORR or show statistical significance in OS for LYNPARZA vs chemotherapy.

AR=adverse reaction; BICR=blinded independent central review; CPS&EG=pre-treatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade; CI=confidence interval; CR=complete response; HER2=human epidermal growth factor receptor 2; HR=hazard ratio or hormone receptor; IDFS=invasive disease-free survival; non-pCR=non-pathologic complete response; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; TNBC=triple negative breast cancer.

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—Adjuvant Treatment of g*BRCA*m, HER2-Negative, High-Risk Early Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: nausea (57%), fatigue (including asthenia) (42%), anemia (24%), vomiting (23%), headache (20%), diarrhea (18%), leukopenia (17%), neutropenia (16%), decreased appetite (13%), dysgeusia (12%), dizziness (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: decrease in lymphocytes (77%), increase in mean corpuscular volume (67%), decrease in hemoglobin (65%), decrease in leukocytes (64%), and decrease in absolute neutrophil count (39%).

ADVERSE REACTIONS—g*BRCA*m, HER2-Negative Metastatic Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: decrease in hemoglobin (82%), decrease in lymphocytes (73%), decrease in leukocytes (71%), increase in mean corpuscular volume (71%), decrease in absolute neutrophil count (46%), and decrease in platelets (33%).

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TEST

Test for g*BRCA* mutations* in patients with HER2-negative breast cancer to help determine eligibility for LYNPARZA[1]

TARGET

Target PARP inhibition for eligible patients with g*BRCA*m HER2-negative breast cancer in both the adjuvant and metastatic settings[1]

TREAT

Treat with LYNPARZA, the only PARPi with indications in both early and metastatic breast cancer[1-4]

Not actual patients.

Choose LYNPARZA for your eligible patients with g*BRCA*m,* HER2-negative breast cancer in the adjuvant or metastatic setting

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

g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); PARP=poly (ADP-ribose) polymerase.

IMPORTANT SAFETY INFORMATION (Cont'd)

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.

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Important Safety Information

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INDICATIONS

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

Adjuvant Treatment of g*BRCA*m, HER2-Negative, High-Risk Early Breast Cancer

For the adjuvant treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

g*BRCA*m, HER2-Negative Metastatic Breast Cancer

For the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. 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 with various *BRCA*m, g*BRCA*m, HRR gene-mutated or HRD-positive cancers who received LYNPARZA 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.

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.

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: 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.

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.

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.

Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

ADVERSE REACTIONS—Adjuvant Treatment of g*BRCA*m, HER2-Negative, High-Risk Early Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: nausea (57%), fatigue (including asthenia) (42%), anemia (24%), vomiting (23%), headache (20%), diarrhea (18%), leukopenia (17%), neutropenia (16%), decreased appetite (13%), dysgeusia (12%), dizziness (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: decrease in lymphocytes (77%), increase in mean corpuscular volume (67%), decrease in hemoglobin (65%), decrease in leukocytes (64%), and decrease in absolute neutrophil count (39%).

ADVERSE REACTIONS—g*BRCA*m, HER2-Negative Metastatic Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: decrease in hemoglobin (82%), decrease in lymphocytes (73%), decrease in leukocytes (71%), increase in mean corpuscular volume (71%), decrease in absolute neutrophil count (46%), and decrease in platelets (33%).

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Important Safety Information (Cont'd)

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IMPORTANT SAFETY INFORMATION (Cont'd)

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 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; 2023. **2.** Rubraca® (rucaparib) [prescribing information]. Vienna, Austria: pharma&, GmbH; 2023. **3.** Talzenna® (talazoparib) [prescribing information]. New York, NY: Pfizer Inc; 2023. **4.** Zejula® (niraparib) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; 2023. **5.** Tutt ANJ, Garber JE, Kaufman B, et al; OlympiA Clinical Trial Steering Committee and Investigators. Adjuvant olaparib for patients with *BRCA1*- or *BRCA2*-mutated breast cancer. *N Engl J Med*. 2021;384(25):2394-2405. **6.** Tutt ANJ, Garber JE, Kaufman B, et al; OlympiA Clinical Trial Steering Committee and Investigators. Adjuvant olaparib for patients with *BRCA1*- or *BRCA2*-mutated breast cancer. Clinical Study Protocol. *N Engl J Med*. 2021;384(25):2394-2405. **7.** Geyer CE Jr, Garber JE, Gelber RD, et al. Overall survival in the OlympiA phase III trial of adjuvant olaparib in patients with germline pathogenic variants in *BRCA1/2* and high-risk, early breast cancer. *Ann Oncol*. 2022;33(12):1250-1268. **8.** Robson M, Im S-A, Senkus E, et al. Olaparib for metastatic breast cancer in patients with a germline *BRCA* mutation. *N Engl J Med*. 2017;377(6):523-533. **9.** Robson ME, Tung N, Conte P, et al. OlympiAD final overall survival and tolerability results: olaparib versus chemotherapy treatment of physician's choice in patients with a germline *BRCA* mutation and HER2-negative metastatic breast cancer. *Ann Oncol*. 2019;30(4):558-566. **10.** Robson M, Im S-A, Senkus E, et al. Olaparib for metastatic breast cancer in patients with a germline *BRCA* mutation. Supplementary Appendix. *N Engl J Med*. 2017;377(6):523-533. **11.** Robson ME, Tung N, Conte P, et al. OlympiAD final overall survival and tolerability results: olaparib versus chemotherapy treatment of physician's choice in patients with a germline *BRCA* mutation and HER2-negative metastatic breast cancer. Supplementary Appendix. *Ann Oncol*. 2019;30(4):558-566.

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In OlympiA

Baseline characteristics of patients[6]

Characteristics	LYNPARZA (n=921)	Placebo (n=915)
Age (years)		
Median	42	43
Interquartile range	(36–49)	(36–50)
Germline *BRCA* mutation type – no. (%)		
BRCA1	657 (71.3)	670 (73.2)
BRCA2	261 (28.3)	239 (26.1)
BRCA1 and *BRCA2*	2 (0.2)	5 (0.5)
Missing data	1 (0.1)	1 (0.1)
Hormone receptor status – no. (%)		
Hormone receptor positive, HER2-negative	168 (18.2)	157 (17.2)
Triple-negative	751 (81.5)	758 (82.8)
Previous adjuvant or neoadjuvant chemotherapy – no. (%)		
Adjuvant	461 (50.1)	455 (49.7)
Neoadjuvant	460 (49.9)	460 (50.3)
Regimen with both anthracycline and taxane	871 (94.6)	849 (92.8)
Anthracycline regimen, without taxane	7 (0.8)	13 (1.4)
Taxane regimen, without anthracycline	43 (4.7)	52 (5.7)
Regimen not reported	0	1 (0.1)
<6 cycles of neoadjuvant or adjuvant therapy	7 (0.8)	15 (1.6)
Platinum-based neoadjuvant or adjuvant therapy		
Yes	247 (26.8)	239 (26.1)
No	674 (73.2)	676 (73.9)

Among all randomized patients (N=1836), 89% had an ECOG PS=0, and 11% had an ECOG PS=1. Among patients with hormone receptor-positive tumors, 90% received concurrent endocrine therapy.[1]

OlympiA was designed to evaluate LYNPARZA as adjuvant therapy in certain patients with gBRCAm,* HER2-negative, high-risk early breast cancer[1]

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CPS&EG score ≥3 was part of the inclusion criteria in OlympiA for patients with HR-positive, HER2-negative eBC who received prior neoadjuvant chemotherapy

Early breast cancer stage, receptor status, and grade scoring requirements for study enrollment[1*]

Stage/Feature		Points
Clinical stage (pre-treatment)	I/IIA	0
	IIB/IIIA	1
	IIIB/IIIC	2
Pathologic stage (post-treatment)	0/I	0
	IIA/IIB/IIIA/IIIB	1
	IIIC	2
Receptor status	ER positive	0
	ER negative	1
Nuclear grade	Nuclear grade 1–2	0
	Nuclear grade 3	1

*Total score of ≥3 required for patients with HR-positive breast cancer.

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. Verify pregnancy status in females of reproductive potential prior to initiating treatment.

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

OlympiAD was designed to evaluate LYNPARZA in certain patients with gBRCAm, HER2-negative metastatic breast cancer[1]

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In OlympiAD

Baseline characteristics of patients[5]

All patients had an ECOG PS of 0 or 1. Among patients who received prior platinum-based chemotherapy, 21% in the LYNPARZA arm and 14% in the chemotherapy arm were treated for metastatic disease, and 7% in each treatment arm were treated for localized disease.

Characteristics	LYNPARZA (n=205)	Physician's choice of chemotherapy (n=97)
Age (years)		
Median	44	45
Range	(22–76)	(24–68)
Germline *BRCA* mutation type – no. (%)		
BRCA1	117 (57.1)	51 (52.6)
BRCA2	84 (41.0)	46 (47.4)
BRCA1 and *BRCA2*	4 (2.0)	0
Hormone receptor status – no. (%)		
Hormone receptor positive, HER2-negative	103 (50.2)	49 (50.5)
Triple-negative	102 (49.8)	48 (49.5)
Previous chemotherapy for metastatic breast cancer – no. (%)	146 (71.2)	69 (71.1)
Previous platinum-based therapy for breast cancer – no. (%)	60 (29.3)	26 (26.8)
≥2 Metastatic sites – no. (%)	159 (77.6)	72 (74.2)
Location of metastasis – no. (%)		
Bone only	16 (7.8)	6 (6.2)
Other*	189 (92.2)	91 (93.8)

*Data for the other category include patients who did not have metastases in the bone, as well as patients who may have had metastases in the bone along with metastases in other locations.

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

OlympiAD was designed to evaluate LYNPARZA in certain patients with gBRCAm, HER2-negative metastatic breast cancer[1]

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OlympiAD was a phase 3, open-label, randomized, controlled, multicenter study[1,8]

SCREENING

REQUIRED PRIOR THERAPY

Patient baseline characteristics ⊕ **Patient eligibility** ⊕

LYNPARZA may be used in eligible patients with g*BRCA*m,* HER2-negative mBC if previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting and endocrine therapy, if appropriate.[1]

	Metastatic TNBC	HR-positive, HER2-negative mBC
Select eligibility criteria[1]	☑ g*BRCA* mutation ☑ Prior chemotherapy (in neoadjuvant, adjuvant, or metastatic setting)	☑ g*BRCA* mutation ☑ Prior chemotherapy (in neoadjuvant, adjuvant, or metastatic setting) ☑ Prior endocrine therapy, if appropriate

***Earliest eligibility for LYNPARZA*[1]**

FIRST-LINE METASTATIC if prior chemotherapy given in the neoadjuvant or adjuvant setting

SECOND-LINE+ METASTATIC‡ if prior chemotherapy given in the neoadjuvant, adjuvant, or metastatic setting

*Select patients for this indication based on an FDA-approved companion diagnostic for LYNPARZA.[1]
‡Second-line+ includes the second line or later lines of treatment.

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.

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).