Lynparza®
olaparib
tablets 150 mg

In the OlympiA trial, up to 1 year* of adjuvant LYNPARZA following neoadjuvant or adjuvant chemotherapy demonstrated

Significant IDFS and OS benefit in patients with g*BRCA*m,† HER2-negative, high-risk‡ eBC vs placebo[1]

†Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.[1]

*Treatment was continued for up to 1 year, or until disease recurrence, or unacceptable toxicity.

IDFS§: PRIMARY ENDPOINT

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]

OS: KEY SECONDARY ENDPOINT

32% Reduction in the risk of death vs placebo
HR=0.68 (95% CI: 0.50–0.91); *P*=0.0091[1]

Follow-up data at 6 years inside

See OlympiA study design, dosing, and results sections for additional information.

Not an actual patient.

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 (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.

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.

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

‡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]

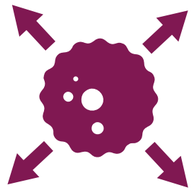
§IDFS was defined as time to first invasive breast cancer recurrence (loco-regional or distant), second primary cancer, or death from any cause.[1]

CI=confidence interval; CPS&EG=pre-treatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade; eBC=early breast cancer; g*BRCA*m=germline *BRCA*-mutated; HER2=human epidermal growth factor receptor 2; HR=hazard ratio or hormone receptor; IDFS=invasive disease-free survival; OS=overall survival; pCR=pathologic complete response; TNBC=triple-negative breast cancer.

gBRCA mutations can elevate disease risks[2]

Adults with *BRCA*m breast cancer may have a higher risk of the following:

Up to 4x higher risk
of contralateral breast cancer recurrence vs non-carriers[3,4]



Higher risk
of developing mBC[5,6]

Higher rates
of brain metastases vs non-carriers[7]

Up to 40%
of g*BRCA*m carriers may develop primary ovarian cancer[2]

g*BRCA* mutations are actionable driver mutations that can inform treatment decisions[2]

HR+

Endocrine therapy alone may not be enough
to reduce the risk of cancer recurrence for certain patients with g*BRCA*m, HR-positive, HER2-negative eBC[1]

Patients with g*BRCAm, regardless of HR expression in HER2-negative subtypes, may benefit from therapy tailored to the drivers of their distinct disease[1]

*BRCA*m=*BRCA*-mutated; g*BRCA*=germline *BRCA*; g*BRCA*m=germline *BRCA*-mutated or germline *BRCA* mutation(s); mBC=metastatic breast cancer.

OlympiA was designed to evaluate LYNPARZA vs placebo 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[1,8]

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

1:1 Randomization within 12 weeks
N=1836

Patient baseline characteristics ⊕ CPS&EG score ⊕

Stratification factors
- HR-positive vs TNBC
- Prior neoadjuvant vs adjuvant chemotherapy
- Prior platinum-based chemotherapy (yes vs no)

LYNPARZA 300 mg BID (n=921)

Placebo BID (n=915)

- LYNPARZA or placebo was given for up to 12 months, or until disease recurrence or unacceptable toxicity
- Concurrent endocrine therapy per current clinical practice guidelines for patients with HR-positive tumors was allowed in both arms

PRIMARY ENDPOINT
- Invasive disease-free survival (IDFS)

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

The OlympiA protocol included patients with HR-positive disease and those with TNBC[1,8]
- Patients with TNBC were included at protocol activation in 2014
- The protocol was 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.[1,8]

*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.[8,9]
‡OS and DDFS were controlled for Type 1 error within a hierarchical statistical analysis in OlympiA.[8]

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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.

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

BID=twice daily.

In OlympiA

Baseline characteristics of patients[8]

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)

Characteristics (Cont'd)	LYNPARZA (n=921)	Placebo (n=915)
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]

ECOG PS=Eastern Cooperative Oncology Group Performance Status.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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.

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

BID=twice daily.

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[1*]

Early breast cancer stage, receptor status, and grade scoring requirements for study enrollment

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.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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.

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

BID=twice daily.

Significantly improved IDFS vs placebo in OlympiA*[1,8]

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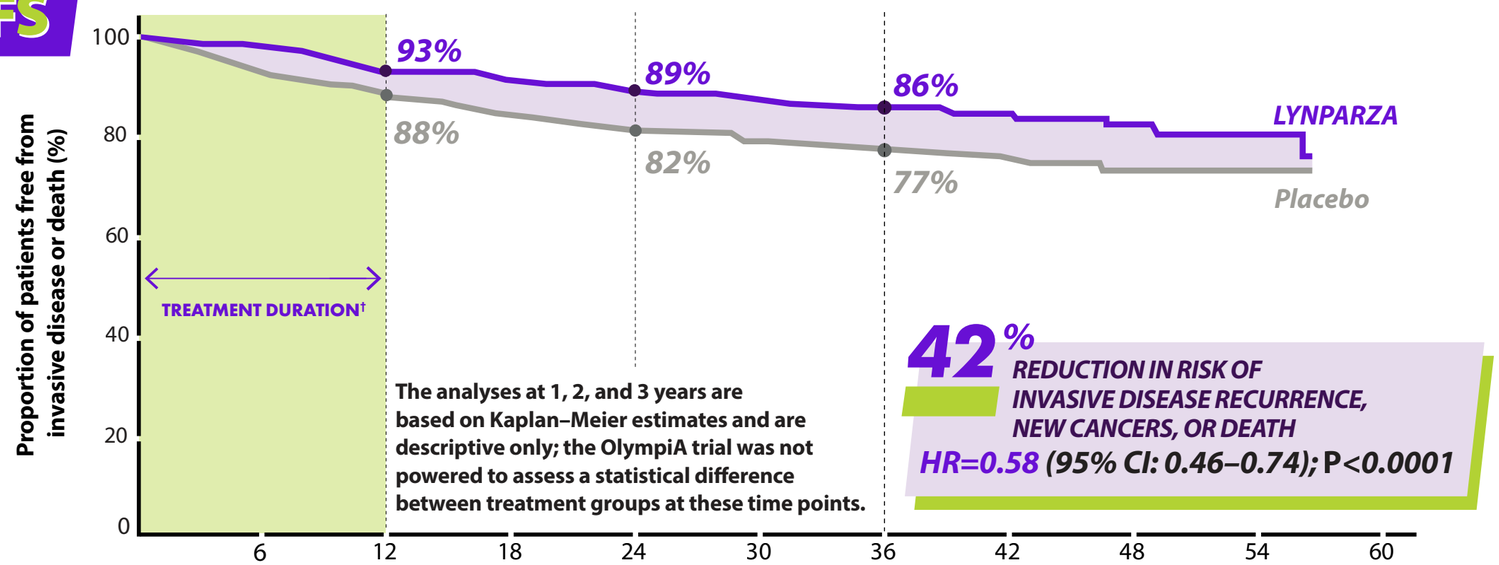
PRIMARY ENDPOINT

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 for 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 prespecified interim analysis (86% of the number of events for the planned final analysis) (median follow-up of 2.5 years)[1,8]

*Invasive disease-free survival was defined as the time to first invasive breast cancer recurrence (locoregional 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]

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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%).

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

*In a 6-year exploratory analysis**

~80% of patients in the LYNPARZA arm and ~70% of patients in the placebo arm were living without an IDFS† event at 6 years[10]

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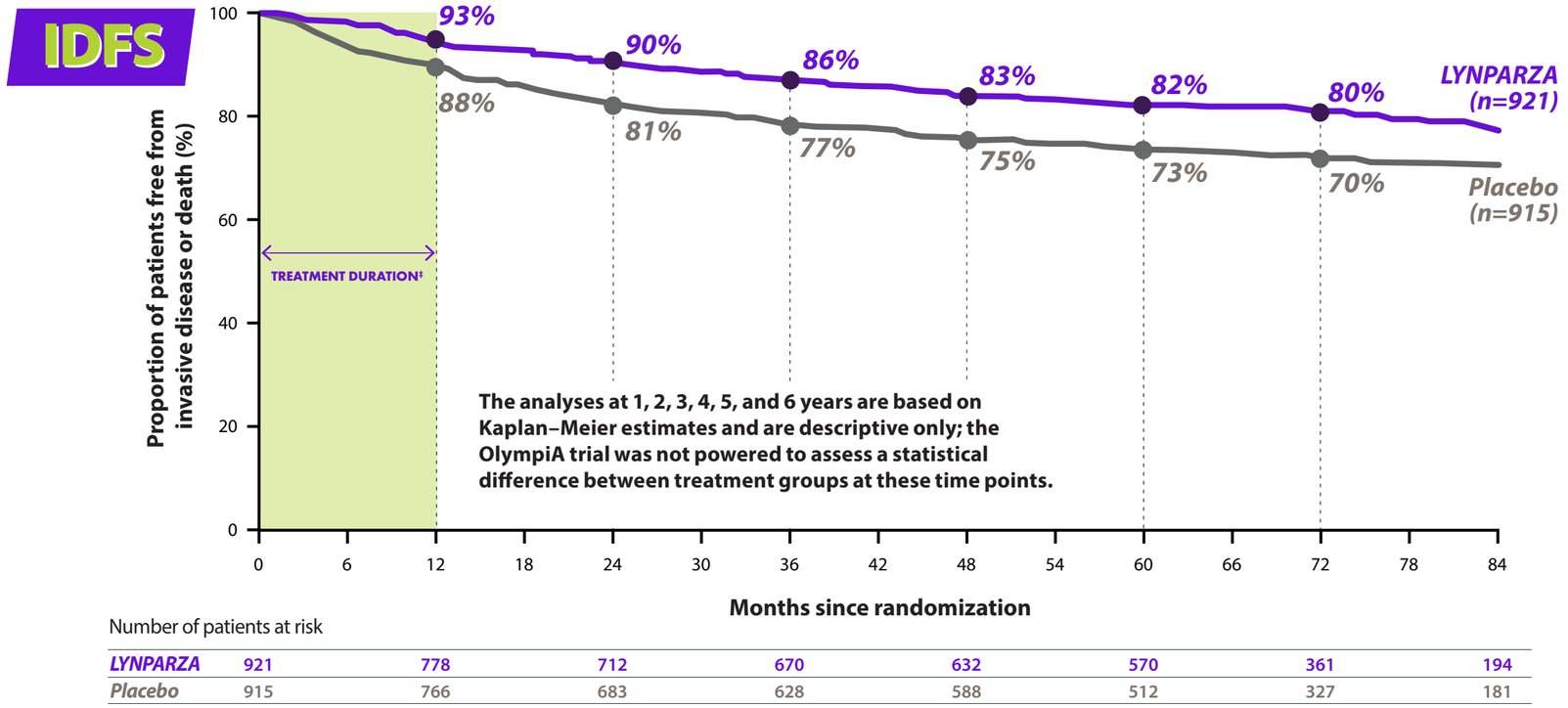
Exploratory (prespecified third) analysis*



Number of patients at risk

LYNPARZA	921	778	712	670	632	570	361	194
Placebo	915	766	683	628	588	512	327	181

- The number of IDFS events observed was 178 (19%) with LYNPARZA vs 258 (28%) with placebo; **HR=0.65 (95% CI: 0.53–0.78)**[10]
- Median IDFS follow-up time (exploratory analysis): 6.1 years[10]

*Efficacy and safety were assessed with follow-up at 10 years from first patient in; DCO3: June 2024.[10]
†Invasive disease-free survival was defined as the time to first invasive breast cancer recurrence (locoregional 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]

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—*gBRCA*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.

For patients who have been treated with neoadjuvant or adjuvant chemotherapy

LYNPARZA is the ONLY targeted adjuvant therapy to achieve OS benefit vs placebo specifically in patients with gBRCAm, HER2-negative, high-risk eBC[1,11-16]

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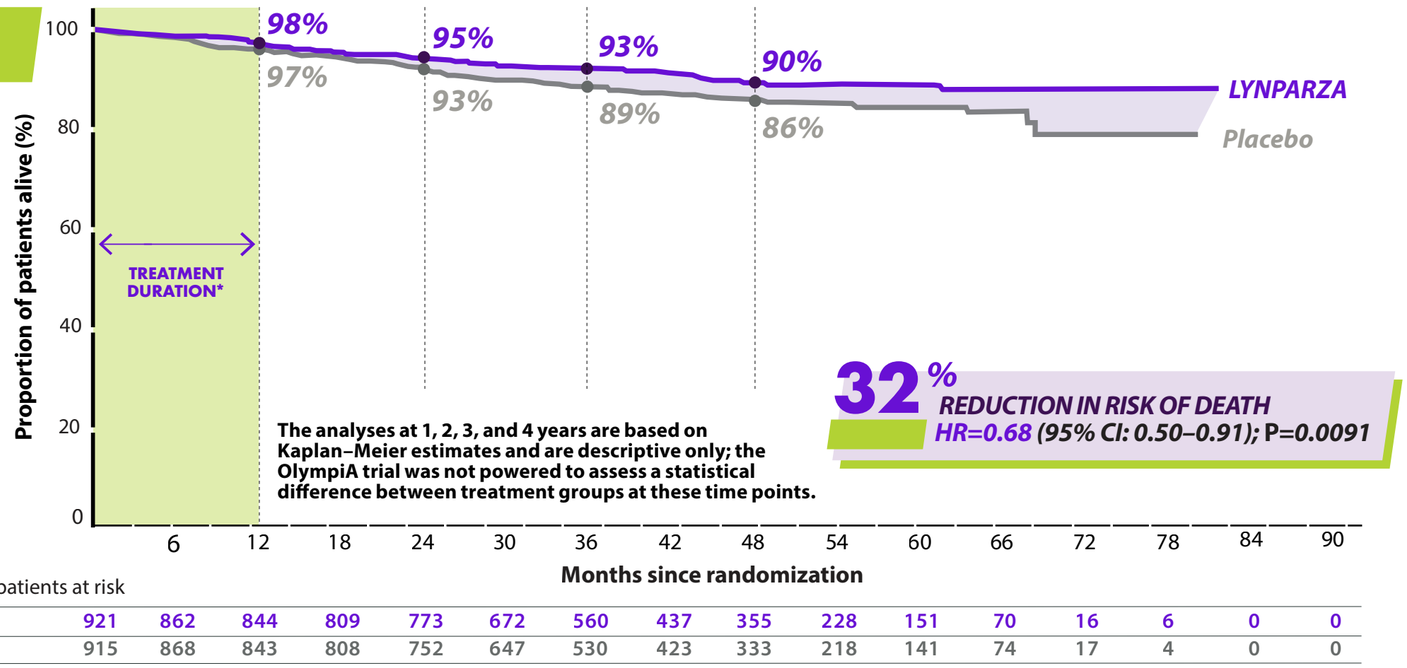
KEY SECONDARY ENDPOINT

OS



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[8]
- 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 prespecified second interim analysis of OS (at ~330 IDFS events) (median follow-up of 3.5 years)[1,11]

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

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

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.

*In a 6-year exploratory analysis**

~88% of patients in the LYNPARZA arm and ~83% of patients in the placebo arm were alive at 6 years[10]

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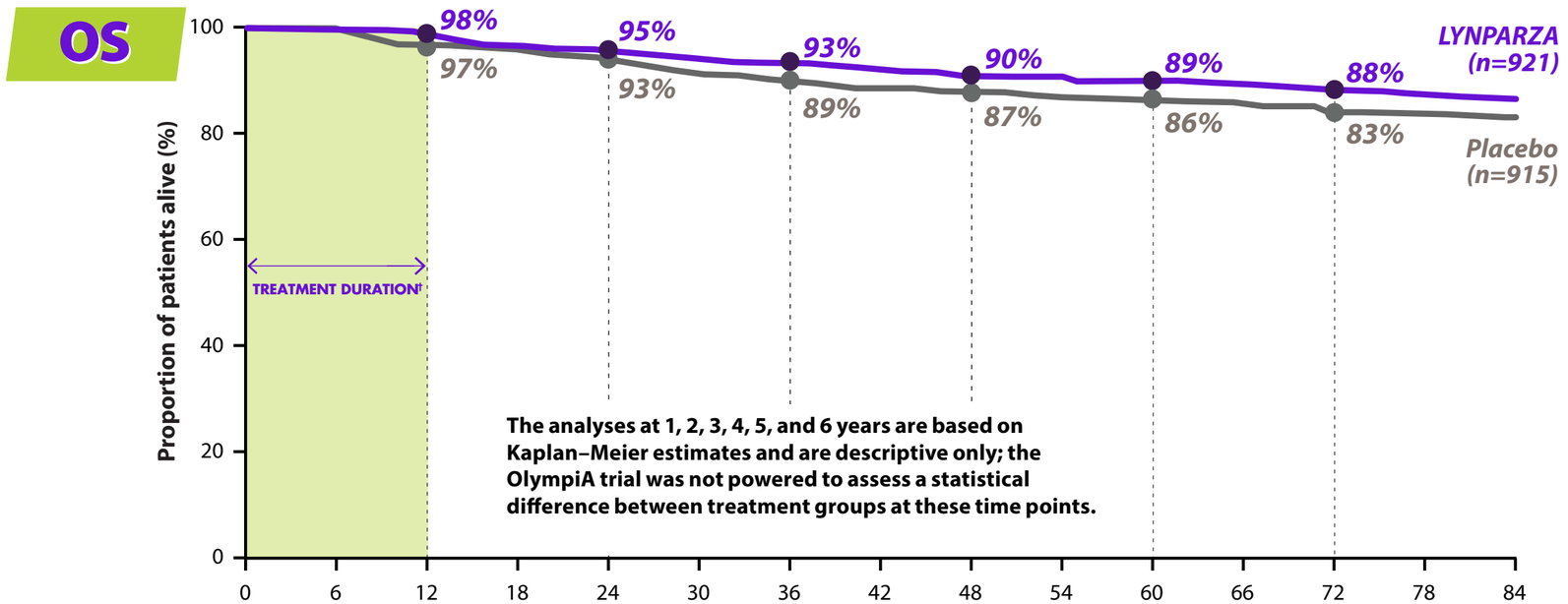
Exploratory (prespecified third) analysis*



Number of patients at risk

LYNPARZA	921	846	795	765	728	660	420	224
Placebo	915	843	788	739	698	616	390	221

- The number of deaths in the LYNPARZA arm was 107 (11.6%) and 143 (15.6%) in the placebo arm; **HR=0.72 (95% CI: 0.56–0.93)**[10]
- Median OS follow-up time (exploratory analysis): 6.1 years[10]

*Efficacy and safety were assessed with follow-up at 10 years from first patient in; DCO3: June 2024.[10]
†LYNPARZA was administered for up to 12 months or until disease recurrence or unacceptable toxicity.[1]

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.

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.

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

DCO=data cutoff.

Select adverse reactions (ARs) in OlympiA

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Primary analysis*: 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]

In an exploratory analysis with a median follow-up of 6.1 years[1,10]:

No new safety signals were identified, and the safety profile remained generally consistent with the primary analysis

- The incidence of MDS/AML was 0.4% in the LYNPARZA group and 0.7% in the placebo group[10]
- The incidence of new primary malignancies (excluding MDS/AML) was 4.9% in the LYNPARZA group and 7.5% in the placebo group[10]
- The incidence of pneumonitis was 1.0% in the LYNPARZA group and 1.4% in the placebo group[10]

*Data from the prespecified analysis at a median follow-up of 2.5 years.[8]
†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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Primary analysis*: Laboratory abnormalities reported in ≥25% of patients in OlympiA[1]

Laboratory parameter‡	LYNPARZA (n=911)† Grades 1–4 (%)	Placebo (n=904)† Grades 1–4 (%)	LYNPARZA (n=911)† Grades 3–4 (%)	Placebo (n=904)† 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

*Data from the prespecified interim analysis (median follow-up 2.5 years).[8]

†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.[1]

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

§Represents the proportion of subjects whose mean corpuscular volume was >ULN.[1]

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

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

Dose modifications due to ARs in OlympiA[1]

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Primary analysis*

	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]

*Data from the prespecified interim analysis at a median follow-up of 2.5 years.[8]

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

AR=adverse reaction.

The majority of patients with gBRCAm HER2-negative breast cancer have HR-positive disease*[17-19]

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Patients with g*BRCA* mutations have a higher risk of recurrence compared to non-carriers, regardless of HR expression in HER2-negative subtypes[7,20,21]

~1 in 10 patients with HER2-negative BC has a g*BRCA* mutation[18,20,22-26]

Among patients with g*BRCA* mutations and HER2-negative breast cancer, more patients have HR-positive disease[18]:

~60%	~40%
HR-positive, HER2-negative	TNBC

- The prevalence of g*BRCA* mutations is higher among patients with **TNBC (~15%)** compared to patients with **HR-positive, HER2-negative disease (~5%)**[27†]
- However, **HR-positive, HER2-negative disease** is **~6x more common** than TNBC[17,19]

†From a systematic review, summarizing international *BRCA1/2* mutation prevalence in breast cancer. In 4 large, unselected studies in TNBC, g*BRCA* mutation prevalence varied from 9.3% (Australia) to 15.4% (US). g*BRCA* mutation prevalence in 1 large, unselected HR-positive, HER2-negative early breast cancer study was 5% (US).[27]

Are you testing all appropriate patients for g*BRCA*m to help inform eligibility for LYNPARZA?

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

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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.

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

BC=breast cancer.

LYNPARZA is recommended for 1 year of treatment in the adjuvant setting*[1]

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RECOMMENDED DAILY DOSE[1]

The recommended daily dose of LYNPARZA is:

300 mg (two 150-mg tablets) taken orally twice daily, with or without food (total 600 mg daily)

Tablets shown are not actual size.

DOSE INTERRUPTION[1]

Consider dose interruption if a patient experiences an AR

See the complete Prescribing Information for detailed dose interruption instructions for select ARs

OR

DOSE REDUCTION[1]

Consider a dose reduction if a patient experiences an AR

INITIAL REDUCTION

Initial reduction to 250 mg (one 150-mg tablet and one 100-mg tablet) taken twice daily (total 500 mg daily)

150 mg
100 mg

FURTHER REDUCTION

Further reduction to 200 mg (two 100-mg tablets) taken twice daily (total 400 mg daily)

100 mg
100 mg

***In the adjuvant setting:** continue LYNPARZA for a total of 1 year, or until disease recurrence or unacceptable toxicity, whichever occurs first

For those patients with g*BRCA*m, HR-positive, HER2-negative early breast cancer,

LYNPARZA may be taken with concurrent endocrine therapy†

†Continue concurrent treatment with endocrine therapy as per current clinical practice guidelines.[1]

This is not all the dosage and administration information necessary to dose LYNPARZA.
Please refer to the dosage and administration section of the Prescribing Information for LYNPARZA.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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%).

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

Choose LYNPARZA for your eligible patients with gBRCAm,* HER2-negative breast cancer[1]

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Not an actual patient.

For high-risk† patients in the adjuvant setting

OlympiA

Primary analysis[1]:

Primary Endpoint: 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: 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%)

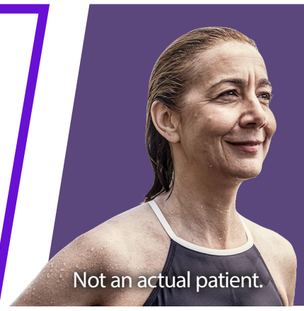
6-year follow-up exploratory analysis[10‡§]:

~80%
of patients were IDFS event-free with LYNPARZA and ~70% were IDFS event-free with placebo[10]

- The number of IDFS events observed was 178 (19%) with LYNPARZA (n=921) and 258 (28%) with placebo (n=915)
- 814 patients (88%) were alive with LYNPARZA and 772 (83%) were alive with placebo

No new safety signals were identified, and the safety profile remained generally consistent with the primary analysis[1,10]

The analysis at 6 years is based on Kaplan–Meier estimates and is descriptive only; the OlympiA trial was not powered to assess a statistical difference between treatment groups at this time point.


Not an actual patient.

Learn about LYNPARZA for certain patients with gBRCAm,* HER2-negative metastatic breast cancer[1]

SEE THE DATA >

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

†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]

‡Efficacy and safety were assessed with follow-up at 10 years from first patient in; DCO3: June 2024.[10]

§Median OS follow-up time (exploratory analysis): 6.1 years.[10]

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—*gBRCA*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.

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 (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.

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.

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.

Important Safety Information (Cont'd)

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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%).

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 complete Prescribing Information, including Medication Guide.

You may report side effects related to AstraZeneca products.

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

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