Dimensions: 11"(w) x 8.5" (h)

An in-office guide to first-line maintenance treatment with

LYNPARZA® (olaparib) FOR ADVANCED OVARIAN CANCER

For healthcare professionals to discuss with their patients

INDICATIONS

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

First-Line Maintenance *BRCA*m Advanced Ovarian Cancer

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

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

In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
- a deleterious or suspected deleterious *BRCA* mutation, and/or
- genomic instability

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

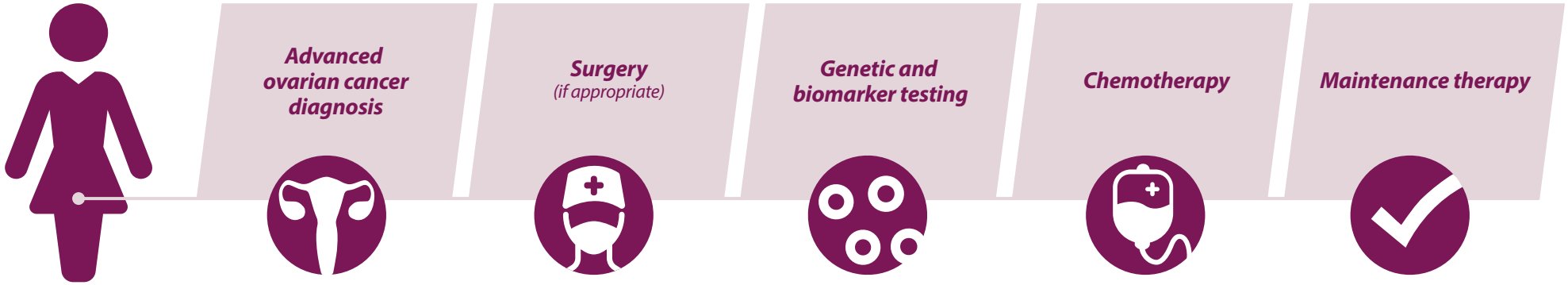
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these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

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 the accompanying complete Prescribing Information, including Medication Guide.

ADVANCED OVARIAN CANCER TREATMENT JOURNEY



This shows a potential treatment path, but every patient is unique, so yours may be different.

GENETIC AND BIOMARKER TESTING MAY HELP WITH TAILORING YOUR TREATMENT PLAN

IN PATIENTS WITH ADVANCED OVARIAN CANCER

BLOOD/SALIVA TEST



~18% have a germline* BRCA *mutation

TUMOR TEST



~25% have a somatic or germline* BRCA *mutation



~50% are HRD positive

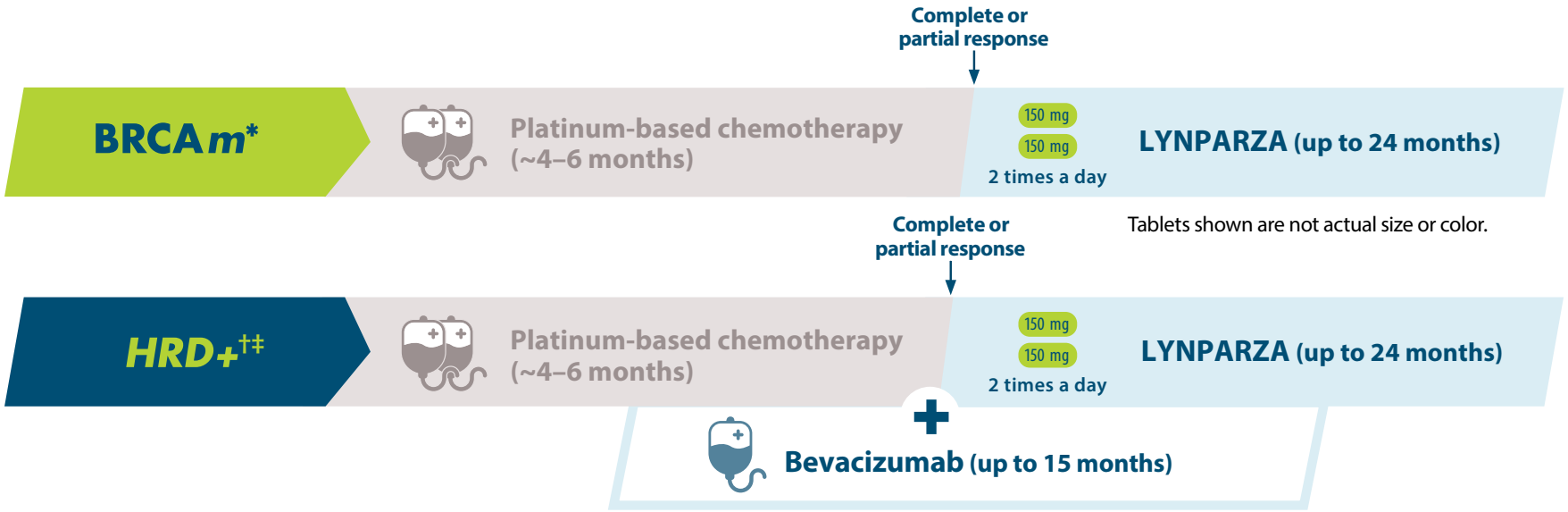
A *BRCA* mutation is a change in the *BRCA* gene that may increase the risk of developing certain types of cancer

- **Germline:** can be passed down by family members
- **Somatic:** occurs randomly and not passed down by family members

An HRD test assesses the DNA profile of the tumor. HRD can be caused by different kinds of mutations, such as a mutation in the *BRCA* gene, or other changes to your tumor's DNA. If a tumor does not have a *BRCA* mutation, it could still be HRD positive

DNA=deoxyribonucleic acid; HRD=homologous recombination deficiency.

GENETIC AND BIOMARKER TEST RESULTS MAY HELP DETERMINE YOUR FIRST-LINE TREATMENT PLAN



*As determined by an FDA-approved blood or tumor sample test.

†Some patients who are HRD positive may also have a *BRCA* mutation and may be able to receive LYNPARZA as a single agent or LYNPARZA + bevacizumab.

‡As determined by an FDA-approved tumor sample test.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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

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

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

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

*BRCA*m=*BRCA* mutated; FDA=US Food and Drug Administration; HRD=homologous recombination deficiency; HRD+=homologous recombination deficiency–positive.

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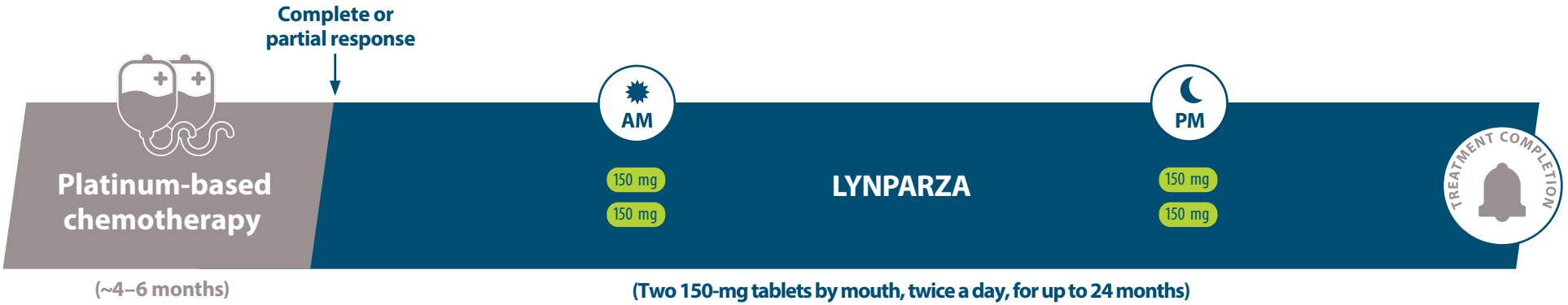
LYNPARZA FIRST-LINE TREATMENT PLAN





- Maintenance treatment with LYNPARZA may be given for up to 24 months. Your doctor will determine how long you will continue treatment with LYNPARZA. Some patients may receive LYNPARZA for more or less time

Tablets shown are not actual size or color.

IMPORTANT SAFETY INFORMATION (Cont'd)

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

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

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

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WHAT IS THE DIFFERENCE BETWEEN INITIAL AND MAINTENANCE TREATMENT?

INITIAL TREATMENT

Platinum-based chemotherapy



Targets quickly dividing cells, including cancer cells

Why initial treatment?

- Initial treatment with platinum-based chemotherapy helps to shrink cancer or kill microscopic disease after surgery

MAINTENANCE TREATMENT

LYNPARZA



LYNPARZA helps stop the repair of damaged cells

Why maintenance treatment?

- Maintenance treatment with LYNPARZA may help keep advanced ovarian cancer from growing or returning, after responding to platinum-based chemotherapy

The exact way LYNPARZA works is unknown.

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.

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

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LYNPARZA IS AN FDA-APPROVED MEDICINE

In a study of *BRCA*m advanced ovarian cancer

The risk of cancer growing or returning was reduced by



70%

with LYNPARZA compared to placebo

The SOLO-1 study tested 391 women with a BRCA *mutation and advanced ovarian cancer after they responded to first-line platinum-based chemotherapy. In this study, 260 women took LYNPARZA and 131 took placebo.*

158 out of 260 women did not see their cancer grow or return at a median follow-up of 3.4 years (41 months) compared to 35 out of 131 women on placebo. This study is still ongoing, but the results at the time the data were assessed are shown above.

Median: the middle number in a list of numbers arranged from lowest to highest.

Placebo: a pill that does not contain active medicine.

IMPORTANT SAFETY INFORMATION (Cont'd)

USE IN SPECIFIC POPULATIONS (Cont'd)

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

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

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

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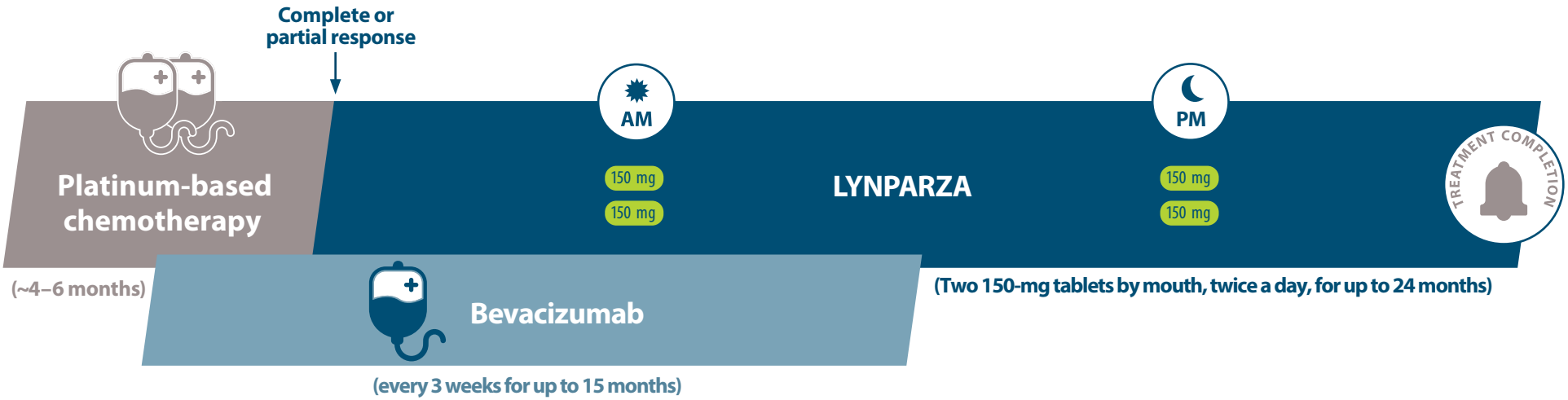
LYNPARZA + BEVACIZUMAB FIRST-LINE TREATMENT PLAN

HRD+ PATIENTS



15 MONTHS

- If bevacizumab is used in combination with LYNPARZA, your doctor will give you an infusion of bevacizumab every 3 weeks. Bevacizumab treatment may be given for up to 15 months

24 MONTHS

- Maintenance treatment with LYNPARZA may be given for up to 24 months. Your doctor will determine how long you will continue treatment with LYNPARZA. Some patients may receive LYNPARZA for more or less time

IMPORTANT SAFETY INFORMATION (Cont'd)

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

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

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

HRD+=homologous recombination deficiency–positive.

WHAT IS THE DIFFERENCE BETWEEN INITIAL AND MAINTENANCE TREATMENT?

INITIAL TREATMENT

Platinum-based chemotherapy



Targets quickly dividing cells, including cancer cells

+

Bevacizumab



Bevacizumab starves the tumor by restricting nutrients and oxygen

Why initial treatment?

- Initial treatment with platinum-based chemotherapy + bevacizumab helps to shrink cancer or kill microscopic disease after surgery

MAINTENANCE

Bevacizumab + LYNPARZA



Bevacizumab starves the tumor by restricting nutrients and oxygen

+



LYNPARZA helps stop the repair of damaged cells

Why maintenance treatment?

- Maintenance treatment with LYNPARZA + bevacizumab may help keep advanced ovarian cancer from growing or returning, after responding to platinum-based chemotherapy

The exact way that LYNPARZA works is unknown.

LYNPARZA and bevacizumab work in 2 distinct ways to treat advanced ovarian cancer.

IMPORTANT SAFETY INFORMATION (Cont'd)

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

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

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

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HRD+=homologous recombination deficiency–positive.

LYNPARZA + BEVACIZUMAB: FDA APPROVED AS A COMBINATION

In patients with HRD+ advanced ovarian cancer
The risk of cancer growing or returning was reduced by



with LYNPARZA + bevacizumab compared to bevacizumab alone

The PAOLA-1 study evaluated advanced ovarian cancer patients who received LYNPARZA + bevacizumab after their tumors responded to first-line platinum-based chemotherapy and bevacizumab. The results shown are from a subset of the LYNPARZA PAOLA-1 study. In the subset of 387 women with HRD-positive advanced ovarian cancer, 255 women received LYNPARZA + bevacizumab and 132 women received bevacizumab + placebo.

*168 out of 255 women on LYNPARZA + bevacizumab did not see their cancer grow or return at a median follow-up of 27.4 months compared to 40 out of 132 women on bevacizumab + placebo.**

Placebo: a pill that does not contain active medicine.
Median: the middle number in a list of numbers arranged from lowest to highest.

*Because of the design of this study, the statistical meaning of these results may be limited.

IMPORTANT SAFETY INFORMATION

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

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

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

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HRD=homologous recombination deficiency; HRD+=homologous recombination deficiency–positive.

SERIOUS AND COMMON SIDE EFFECTS OF LYNPARZA

SERIOUS SIDE EFFECTS

LYNPARZA may cause serious side effects, including:

Bone marrow problems called myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML).

Some people who have ovarian cancer or breast cancer and who have received previous treatment with chemotherapy, radiotherapy, or certain other medicines for their cancer have developed MDS or AML during treatment with LYNPARZA. MDS or AML may lead to death. If MDS or AML develops, treatment with LYNPARZA should be stopped.

Symptoms of low blood cell counts are common during treatment with LYNPARZA, but can be a sign of serious bone marrow problems, including MDS or AML.

Symptoms may include:

- Weakness
- Weight loss
- Fever
- Frequent infections
- Blood in urine or stool
- Shortness of breath
- Feeling very tired
- Bruising or bleeding more easily

Blood tests to check blood counts will be performed:

- Before treatment with LYNPARZA
- Every month during treatment with LYNPARZA
- Weekly if low blood cell counts last a long time. Treatment with LYNPARZA may be stopped until blood cell counts improve

Lung problems (pneumonitis)

Tell your healthcare provider if you have any new or worsening symptoms of lung problems, including shortness of breath, fever, cough, or wheezing. A chest X-ray may be performed if these symptoms occur.

Your healthcare provider may temporarily or completely stop treatment if you develop pneumonitis. Pneumonitis may lead to death.

COMMON SIDE EFFECTS

The most common side effects of LYNPARZA are:

- Nausea or vomiting
- Tiredness or weakness
- Low red blood cell counts
- Diarrhea
- Loss of appetite
- Headache
- Low white blood cell counts
- Changes in the way food tastes
- Cough
- Dizziness
- Shortness of breath
- Indigestion or heartburn

These are not all of the possible side effects of LYNPARZA. Side effects may be reported to FDA at 1-800-FDA-1088.

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MANAGING SOME OF THE MOST COMMON SIDE EFFECTS OF LYNPARZA

Call your healthcare provider for medical advice about side effects.

Anemia

- Eat foods that are high in iron, including leafy vegetables, sweet potatoes, prunes, beans, meat, and fish
- Speak to your physician about the use of medication or supplements for the treatment of anemia

Fatigue

- Try to eat foods that contain protein
- Balance daily routine with both rest and physical activity
- Try light exercise every day, with plenty of short naps or breaks



Nausea or vomiting

- Eat smaller meals and foods that are easy on the stomach, such as clear broth or toast
- Stay hydrated by drinking plenty of water and other caffeine-free, clear liquids
- Avoid foods with strong odors
- Sit up or recline with head raised for at least an hour after eating
- Take any medications your doctor has prescribed to treat nausea or vomiting

Notify your care team immediately of any side effects that you experience, including the ones listed here or any others.

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LYNPARZA CAN BE A PART OF YOUR DAILY ROUTINE

It's 2 tablets, taken by mouth twice a day, with or without food



2 TABLETS
in the morning
(300 mg)

2 TABLETS
in the evening
(300 mg)

Tablets shown are not actual size or color.

Take LYNPARZA exactly as your doctor tells you: 2 tablets (150 mg each) 2 times a day (300 mg per dose), totaling 4 tablets each day by mouth (600 mg daily dose)

Additional things to remember when taking LYNPARZA:

- Swallow the tablets whole—do not chew, crush, dissolve, or divide them
- Take each dose about 12 hours apart, with or without food
- Do not take more than 4 tablets a day
- Do not change your dose or stop taking LYNPARZA unless your prescriber tells you to. Your doctor may temporarily stop treatment with LYNPARZA or change your dose of LYNPARZA if you experience side effects



DO NOT EAT OR DRINK
Grapefruit, grapefruit juice, Seville oranges, or Seville orange juice. They may increase the levels of LYNPARZA in your blood



IF YOU MISS A DOSE
Take your next dose at the usual scheduled time. Do not take an extra dose to make up for the one you missed



IF YOU TAKE TOO MUCH
Call your doctor or go to the nearest hospital emergency room right away



Tell your doctor about all the medicines you take and medical conditions that you have

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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.

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

Females

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

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

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IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—First-Line Maintenance *BRCA*m Advanced Ovarian Cancer (cont'd)

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

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

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

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

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

DRUG INTERACTIONS

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

MERCK AstraZeneca

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