LYNPARZA® (olaparib) is the first and only PARPi indicated for the adjuvant treatment of patients with gBRCAm, HER2-negative, high-risk† early breast cancer (eBC)

LYNPARZA is indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, 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.

Olympia trial overview

- Patient population included those with gBRCAm, HER2-negative (TNBC or HR-positive), high-risk† eBC
- Neoadjuvant Chemotherapy
- SURGERY
- Adjuvant Chemotherapy
- Prior therapy
- For up to 12-month duration or disease recurrence or unacceptable toxicity
- LYNPARZA 300 mg BID n=921
- Placebo n=915
- +ET per current clinical practice guidelines for HR-positive patients

Primary endpoint: IDFS

<table>
<thead>
<tr>
<th>LYNPARZA (n=911)</th>
<th>Placebo (n=904)</th>
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</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>Grades 1-4 (%)</td>
</tr>
<tr>
<td>Fatigue (including asthenia)</td>
<td>42</td>
</tr>
<tr>
<td>Anemia</td>
<td>24</td>
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<tr>
<td>Vomiting</td>
<td>23</td>
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<tr>
<td>Headache</td>
<td>20</td>
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<tr>
<td>Diarrhea</td>
<td>18</td>
</tr>
<tr>
<td>Leukopenia‡</td>
<td>16</td>
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<tr>
<td>Neutropenia§</td>
<td>16</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>13</td>
</tr>
<tr>
<td>Dysgeusia¶</td>
<td>12</td>
</tr>
<tr>
<td>Dizziness</td>
<td>11</td>
</tr>
<tr>
<td>Stomatitis††</td>
<td>10</td>
</tr>
</tbody>
</table>

Adverse reactions leading to death were cardiac arrest in 1 patient who received LYNPARZA and AML/ovarian cancer in 1 patient each who received placebo.

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

†Includes anemia, anemia macrocytic, erythropenia, hematocrit decreased, hemoglobin decreased, normochromic normocytic anemia, normochromic 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, neutropenia infection, neutropenic sepsis, neutrophil count decreased.

¶Includes dysgeusia, taste disorder.

††Includes aphthous ulcer, mouth ulceration, stomatitis.

Additional Important Safety Information

- 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.

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.

Please see additional Important Safety Information on reverse side and complete Prescribing Information, including Medication Guide.

BID=twice daily; CI=confidence interval; DFS=distal disease-free survival; DFS=disseminated disease-free survival; ET=endocrine therapy; gBRCAm=germline breast cancer susceptibility gene mutated; HER2=human epidermal growth factor receptor 2; HR=hazard ratio; HR-positive=HR-positive receptor positive; IDFS=invasive disease-free survival; non-pCR=pathologic non-complete response; OS=overall survival; PARPi=poly (ADP-ribose) polymerase inhibitor; TNBC=triple-negative breast cancer.

†For patients who received prior neoadjuvant chemotherapy, high risk was defined as non-pCR in TNBC and as non-pCR with CP/SGS 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.

‡For patients who received prior neoadjuvant chemotherapy, high risk was defined as non-pCR in TNBC and as non-pCR with CP/SGS 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.

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

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#Includes dysgeusia, taste disorder.

*Includes aphthous ulcer, mouth ulceration, stomatitis.

3At least 6 cycles of neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes, or both agents. Platinum-based chemotherapy was allowed.

4Radiation therapy was given when appropriate.
Dose reductions are based on investigator-initiated decisions. Reductions due to patient noncompliance are omitted.

Patients in the OlympiA trial did not receive capecitabine, thus there are no data on sequencing or to guide selection of one over the other.

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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
Advising 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.

Advise males 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 gBRCAm, HER2-negative, high-risk eBC, 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 on reverse side and complete Prescribing Information, including Medication Guide.

You may report side effects related to AstraZeneca products by clicking here. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.