LYNPARZA™ (olaparib) Capsules Fact Sheet

ABOUT LYNPARZA[1]

- LYNPARZA is approved as a monotherapy in patients with deleterious or suspected deleterious germline *BRCA* (gBRCA) mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
  - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- The dosage of LYNPARZA is 400 mg (eight 50 mg capsules) twice daily, offering patients oral administration with recommended treatment until progression of disease or unacceptable toxicity.

EXISTING LYNPARZA DATA[1]

- LYNPARZA demonstrated an objective response rate of 34% (95% CI: 26, 42) in 137 patients with gBRCAm ovarian cancer who received three or more prior lines of chemotherapy. The median duration of response was 7.9 months (95% CI: 5.6, 9.6).
- Some people who have ovarian cancer or who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed bone marrow problems called Myelodysplastic syndrome (MDS) or Acute Myeloid Leukemia (AML) during treatment with LYNPARZA. 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.

ABOUT PARP INHIBITORS AND BRCA STATUS

- LYNPARZA is an inhibitor of poly ADP-ribose polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, and DNA repair.[1]
- In the general population, 1.4% of women will be diagnosed with ovarian cancer, while up to 40% of women with BRCA 1/2 mutations will be diagnosed with ovarian cancer in their lifetime.[2]
- Up to 15% of women with ovarian cancer have a BRCA mutation, which is the most common cause of homologous repair deficiency.[2] In BRCA-mutated tumor cells, homologous recombination is defective and DNA double-strand break repair is forced to occur via error-prone pathways, which can lead to genomic instability and cell death.[3]
- BRCA mutations can be identified through genetic testing.[4]

CLINICAL & REGULATORY PLANS

- AstraZeneca is committed to addressing the unmet need for ovarian cancer patients and further evaluating the clinical profile of LYNPARZA.

Important Safety Information

There are no contraindications for LYNPARZA.

LYNPARZA may cause serious side effects that can lead to death including bone marrow problems and lung problems. Some people who have ovarian cancer or who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed bone marrow problems called Myelodysplastic syndrome (MDS) or Acute

Myeloid Leukemia (AML) during treatment with LYNPARZA. 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.
You will undergo blood tests before, and every month during, treatment with LYNPARZA to monitor your blood cell counts. Symptoms to discuss with your healthcare provider include weakness, weight loss, fever, frequent infections, blood in your urine/stool, shortness of breath, feeling very tired, and bruising or bleeding more easily.

Tell your healthcare provider if you have any new or worsening symptoms of lung problems, including shortness of breath, fever, cough, or wheezing.

Avoid pregnancy when taking LYNPARZA and tell your healthcare provider right away if you are, or think you have become, pregnant.

Avoid grapefruit, grapefruit juice and Seville oranges during treatment as they may increase the levels of LYNPARZA in your blood.

The most common side effects are anemia, nausea or vomiting, tiredness or weakness, diarrhea, indigestion or heartburn, headache, loss of appetite, changes in how food tastes, changes in kidney function blood tests, sore throat or runny nose, upper respiratory infection, cough, pain in the joints, muscles, and back, rash, and pain or discomfort in the stomach area.

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

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit www.astrazeneca-us.com.

LYNPARZA™ is a registered trademark of the AstraZeneca group of companies.

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[1] LYNPARZA full Prescribing Information. AstraZeneca Pharmaceuticals LP, Wilmington, DE.
[2] National Cancer Institute. BRCA1 and BRCA2: Cancer Risk and Genetic Testing. http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA. Accessed November 12, 2014.
[3] Burgess, M, Puhalla, S. BRCA ½-mutation related and sporadic breast and ovariancancers: more alike than different. *Frontiers in Oncology* 2014.
[4] Gadzicki D, et al. Genetic testing for familial/hereditary breast cancer—comparison of guidelines and recommendations from the UK, France, the Netherlands and Germany. *J Community Genet*. 2011;2:53-69.