Lynparza® (olaparib) – New indication

- On May 8, 2020, AstraZeneca announced the FDA approval of Lynparza (olaparib), in combination with bevacizumab (eg, Avastin®) 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.

    — Patients should be selected for therapy based on an FDA-approved companion diagnostic for Lynparza.

- Lynparza is also approved for first-line maintenance treatment of *BRCA*-mutated advanced ovarian cancer; maintenance treatment of recurrent ovarian cancer; advanced germline *BRCA*-mutated ovarian cancer after 3 or more lines of chemotherapy; germline *BRCA*-mutated HER2-negative metastatic breast cancer; and first-line maintenance treatment of germline *BRCA*-mutated metastatic pancreatic adenocarcinoma.

- The approval of Lynparza for the new indication was based on a randomized, double-blind, placebo-controlled study in patients with advanced high-grade epithelial ovarian cancer, fallopian tube or primary peritoneal cancer following first-line platinum-based chemotherapy and bevacizumab. Patients received Lynparza plus bevacizumab or placebo plus bevacizumab for maintenance treatment. The major efficacy outcome measure was progression free survival (PFS). Efficacy results from a biomarker subgroup analysis of 387 patients with HRD positive tumors were reported.

    — Median PFS was 37.2 months vs. 17.7 months for the Lynparza and placebo groups, respectively (hazard ratio 0.33, 95% CI: 0.25, 0.45).
    — Overall survival data in this subpopulation were immature with 16% deaths.

- The most common adverse reactions (≥ 10%) with Lynparza use in combination with bevacizumab were nausea, fatigue (including asthenia), anemia, lymphopenia, vomiting, diarrhea, neutropenia, leukopenia, urinary tract infection, and headache.

- The recommended dose of Lynparza for first-line maintenance treatment of advanced ovarian cancer in combination with bevacizumab is 300 mg taken orally twice daily, with or without food. Lynparza treatment should be continued until disease progression, unacceptable toxicity, or completion of 2 years of treatment.

    — Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous Lynparza treatment, can be treated beyond 2 years.
    — Information on FDA-approved tests for the detection of *BRCA* mutations or genomic instability are available at http://www.fda.gov/companiondiagnostics.
    — When used with Lynparza, the recommended dose of bevacizumab is 15 mg/kg every three weeks. Bevacizumab should be given for a total of 15 months including the period given with chemotherapy and given as maintenance. Refer to the drug label for bevacizumab for more information.

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— Refer to the Lynparza drug label for dosing for all its other indications.