FDA Approves Lynparza Plus Bevacizumab for Ovarian Cancer Maintenance Treatment

The PARP inhibitor delayed disease progression by 20 months compared with a placebo.

May 12, 2020 By Food and Drug Administration (FDA)

FDA approves olaparib plus bevacizumab as maintenance treatment for ovarian, fallopian tube, or primary peritoneal cancers

On May 8, 2020, the Food and Drug Administration expanded the indication of olaparib (LYNPARZA, AstraZeneca Pharmaceuticals, LP) to include its combination with bevacizumab for first-line 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 positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability.

FDA also approved the Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.) as a companion diagnostic for olaparib.

Efficacy of this new indication was investigated in PAOLA-1 (NCT03737643), a randomized, double-blind, placebo-controlled, multi-center trial comparing olaparib with bevacizumab versus placebo plus bevacizumab in patients with advanced high-grade epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer following first-line platinum-based chemotherapy and bevacizumab.

Randomization was stratified by first-line treatment outcome and tumor BRCA mutation (tBRCAm) status, determined by prospective local testing. All available clinical samples were retrospectively tested with Myriad myChoice CDX test.

Patients were randomized (2:1) to receive olaparib tablets 300 mg orally twice daily in combination with bevacizumab (n=537) 15 mg/kg every three weeks or placebo plus bevacizumab (n=269). Patients continued bevacizumab in the maintenance setting and started olaparib after a minimum of 3 weeks and up to a maximum of 9 weeks following their last chemotherapy dose. Olaparib was continued for up to 2 years or until disease progression or unacceptable toxicity.

The major efficacy outcome measure was investigator-assessed progression-free survival (PFS)

evaluated according to RECIST 1.1. An additional efficacy endpoint was overall survival (OS). Estimated median PFS in the subgroup of 387 patients with HRD-positive tumors was 37.2 months in the olaparib with bevacizumab arm and 17.7 months in the placebo plus bevacizumab arm (HR 0.33; 95% CI: 0.25-0.45). Results from a blinded independent review of PFS were consistent with the investigator-assessed PFS analysis. OS data were not mature.

The most common adverse reactions in the olaparib with bevacizumab treatment (≥10% of patients) were nausea, fatigue (including asthenia), anemia, lymphopenia, vomiting, diarrhea, neutropenia, leukopenia, urinary tract infection, and headache.

The recommended olaparib dose is 300 mg taken orally twice daily, with or without food. When used with olaparib, the recommended bevacizumab dose is 15 mg/kg intravenously every three weeks.

View full prescribing information for LYNPARZA.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

FDA granted this application priority review and orphan product designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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