FDA Approves Rubraca for Ovarian Cancer Maintenance Treatment

Study showed patients receiving rucaparib had significant improvement in progression-free survival.

April 9, 2018 By Food and Drug Administration (FDA)

FDA approves rucaparib for maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer

On April 6, 2018, the Food and Drug Administration approved rucaparib (Rubraca®, Clovis Oncology Inc.), a poly ADP-ribose polymerase (PARP) inhibitor, for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Approval was based on ARIEL3 (NCT01968213), a randomized, double-blind, placebo-controlled trial in 561 patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who had been treated with at least two prior treatments of platinum-based chemotherapy and were in complete or partial response to the most recent platinum-based chemotherapy. Patients were randomized (2:1) to rucaparib 600 mg orally twice daily (n=372) or placebo (n=189) and were treated until disease progression or unacceptable toxicity.

Tumor tissue samples were examined with a next-generation sequencing assay to determine whether DNA contained a deleterious somatic or germline BRCA mutation (tBRCA). This test was also used to determine the percentage of genomic loss of heterozygosity (LOH). Positive homologous recombination deficiency (HRD) status was defined as tBRCA-positive and/or LOH high. Three patient outcomes analyses were performed on the following groups: all patients, HRD subgroup, and tBRCA subgroup.

ARIEL3 demonstrated a statistically significant improvement in estimated median progression-free survival (PFS) assessed by investigator for patients randomized to rucaparib compared with placebo in all patients (median PFS 10.8 vs. 5.4 months, HR 0.36; 95% CI:0.30, 0.45; p<0.0001), in the HRD subgroup (median PFS 13.6 vs. 5.4 months, HR 0.32; 95% CI: 0.24, 0.42; p<0.0001), and in the tBRCA subgroup (median PFS 16.6 vs. 5.4 months, HR 0.23; 95% CI: 0.16, 0.34; p <0.0001).

The FDA also concurrently approved the complementary diagnostic test,

FoundationFocus™ CDx $_{\text{BRCA LOH}}$, for tumor samples to determine HRD status.

In ARIEL3, the most common adverse reactions in at least 20% of patients treated with rucaparib included nausea, fatigue (including asthenia), abdominal pain/distension, rash, dysgeusia, anemia, ALT/AST elevation, constipation, vomiting, diarrhea, thrombocytopenia, nasopharyngitis/URI, stomatitis, decreased appetite, and neutropenia. Myelodysplastic syndrome and/or acute myeloid leukemia occurred in 7 of 372 (1.9%) patients treated with rucaparib and in 1 of 189 (0.5%) patients assigned to placebo. Discontinuation due to adverse reactions occurred in 15% of patients receiving rucaparib and 2% of those assigned to placebo.

The recommended rucaparib dose is 600 mg (two 300 mg tablets) taken orally twice daily with or without food.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209115s003lbl.pdf.

FDA granted this application priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

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 by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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This announcement originally appeared on the Food and Drug Administration website on April 6, 2018.

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