Generic Name:
Rucaparib
Trade Name:
Rubraca
Company:
Clovis Oncology
Notes:

FDA approved rucaparib, a poly adenosine diphosphate (ADP)-ribose polymerase (PARP) inhibitor, for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who achieved 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, in the HRD subgroup, and in the tBRCA subgroup.

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.

Medication Monitor Categories:
Supplemental Approvals

Source URL: http://aphadruginfoline.com/supplemental-approvals/agent-now-approved-treat-recurrent-ovarian-fallopian-tube-or-primary