



Rubraca® (rucaparib) – New indication

- On April 6, 2018, [Clovis Oncology announced](#) the FDA approval of [Rubraca \(rucaparib\)](#) for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
 - Rubraca is also approved for the treatment of adults patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies.
 - The approval for the BRCA-mutated ovarian cancer indication has been converted from accelerated to regular approval.
- The efficacy of Rubraca for the new indication is based on a clinical study of 564 patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who responded to platinum-based chemotherapy, randomized to Rubraca or placebo. The major efficacy measure was progression free survival (PFS).
 - The Rubraca group demonstrated a statistically significant improvement in PFS vs. placebo (HR = 0.36, 95% CI: 0.30, 0.45, $p < 0.0001$). There were fewer PFS events with Rubraca vs. placebo (62% vs. 88%, respectively).
 - The median PFS was 10.8 months with Rubraca vs. 5.4 months with placebo.
 - At the time of the analysis of PFS, overall survival data were not mature.
- The recommended dose of Rubraca for all indications is 600 mg (two 300 mg tablets) taken orally twice daily. Treatment is continued until disease progression or unacceptable toxicity.



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