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.