Rubraca® (rucaparib) – New indication

- On May 15, 2020, Clovis Oncology announced the FDA approval of Rubraca (rucaparib), for the treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
    - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Rubraca is also approved for:
    - 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.
    - Treatment of adult patients with a 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.
- Approximately 43,000 men in the U.S. are expected to be diagnosed with mCRPC in 2020. According to the American Cancer Society, the five-year survival rate for mCRPC is approximately 30%.
    - Approximately 12% of patients with mCRPC harbor a deleterious germline and/or somatic mutation in the genes *BRCA1* and *BRCA2*.
- Rubraca is the first poly (ADP-ribose) polymerase (PARP) inhibitor approved in a prostate cancer setting.
- The approval of Rubraca for the new indication was based on TRITON2, an ongoing, single-arm study in patients with *BRCA*-mutated mCRPC who had been treated with androgen receptor-directed therapy and taxane-based chemotherapy. There were 115 patients with either germline or somatic *BRCA* mutations enrolled in TRITON2, of whom 62 patients had measurable disease at baseline. Patients received Rubraca until disease progression or unacceptable toxicity. Patients also received concomitant gonadotropin-releasing hormone (GnRH) analog or had prior bilateral orchiectomy. The major efficacy outcomes were confirmed objective response rate (ORR) and duration of response (DOR).
    - In the 62 patients with measurable disease at baseline, the confirmed ORR was 44% (95% CI: 31, 57). The median DOR was not evaluable (95% CI: 6.4, not evaluable).
- The most common adverse reactions (≥ 20%) with Rubraca use among patients with *BRCA*-mutated mCRPC were fatigue (including asthenia), nausea, anemia, increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST), decreased appetite, rash, constipation, thrombocytopenia, vomiting, and diarrhea.
- The recommended dose of Rubraca for all indications is 600 mg (two 300 mg tablets) taken orally twice daily with or without food, for a total daily dose of 1,200 mg. Treatment should be continued until disease progression or unacceptable toxicity.

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- Patients should be selected for the treatment of mCRPC with Rubraca based on the presence of a deleterious *BRCA* mutation (germline and/or somatic). An FDA-approved test for the detection of *BRCA1/BRCA2* mutations in patients with mCRPC is not currently available.
- Patients receiving Rubraca for mCRPC should also receive a GnRH analog concurrently or should have had bilateral orchiectomy.

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