RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Rubraca (rucaparib) Tablets
Clinical Update

Clinical Update: FDA Approved Rubraca (rucaparib) as Monotherapy Treatment for Patients with BRCA1/2-Mutant, Metastatic Castration-Resistant Prostate Cancer (mCRPC).
FDA approval date: May 15, 2020

Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of ovarian cancer and prostate cancer as monotherapy, and in combination with other anti-cancer agents.

Clovis Oncology's Rubraca® (rucaparib) tablets has been approved 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. The FDA approval is based on efficacy data from patients with mCRPC and a deleterious BRCA mutation (germline and/or somatic) enrolled in the multi-center, single arm TRITON2 clinical trial. The major efficacy outcomes are confirmed ORR and DOR by modified RECIST version 1.1/PCWG3 criteria assessed by blinded independent radiologic review (IRR). Confirmed prostate-specific antigen (PSA) response rate is an additional prespecified endpoint. The most common adverse reactions (greater than or equal to 20% of patients; CTCAE Grade 1-4) occurring in the BRCA mutant population (n=115) were asthenia/fatigue, nausea, anemia, ALT/AST increased, decreased appetite, constipation, rash, thrombocytopenia, vomiting, and diarrhea. The most common laboratory abnormalities (greater than or equal to 35% of patients; CTCAE Grade 1-4) were increase in ALT, decrease in leukocytes, decrease in phosphate, decrease in absolute neutrophil count, decrease in hemoglobin, increase in alkaline phosphatase, increase in creatinine, increase in triglycerides, decrease in lymphocytes, decrease in platelets, and decrease in sodium.

Warning and precautions include myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) and embryo-fetal toxicity.