# FDA Approves Rubraca for BRCA-Mutated Metastatic Prostate Cancer

More than 40% of people treated with the PARP inhibitor saw tumor shrinkage.

May 18, 2020 By Food and Drug Administration (FDA)

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FDA grants accelerated approval to rucaparib for BRCA-mutated metastatic castration-resistant prostate cancer

On May 15, 2020, the Food and Drug Administration granted accelerated approval to rucaparib (RUBRACA, Clovis Oncology, Inc.) for patients with 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.

Efficacy was investigated in TRITON2 (NCT02952534), an ongoing, multi-center, single arm clinical trial in 115 patients with BRCA-mutated (germline and/or somatic) mCRPC who had been treated with androgen receptor-directed therapy and taxane-based chemotherapy. Patients received rucaparib 600 mg orally twice daily and concomitant GnRH analog or had prior bilateral orchiectomy.

Objective response rate (ORR) and duration of response (DOR) were assessed in 62 patients with measurable disease. The confirmed ORR was 44% (95% CI: 31, 57). Median DOR was not evaluable (NE; 95% CI: 6.4, NE). The range for the DOR was 1.7-24+ months. Fifteen of the 27 (56%) patients with confirmed objective responses had a DOR of ≥6 months.

The most common adverse reactions (≥ 20%) among all 115 patients with BRCA-mutated mCRPC were fatigue, nausea, anemia, increased ALT/AST, decreased appetite, rash, constipation, thrombocytopenia, vomiting, and diarrhea.

The recommended rucaparib dose is 600 mg orally twice daily with or without food. Patients receiving rucaparib for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

View full prescribing information for Rubraca.

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.

Rucaparib previously was granted Breakthrough Therapy designation for this indication. This application was granted priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

This announcement was originally published on the Food and Drug Administration website on May 15, 2020.

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