TRITON2

A Phase 2, Multicenter, Open-Label Study of Rucaparib in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Associated with Homologous Recombination Deficiency (HRD)

RUCAPARIB

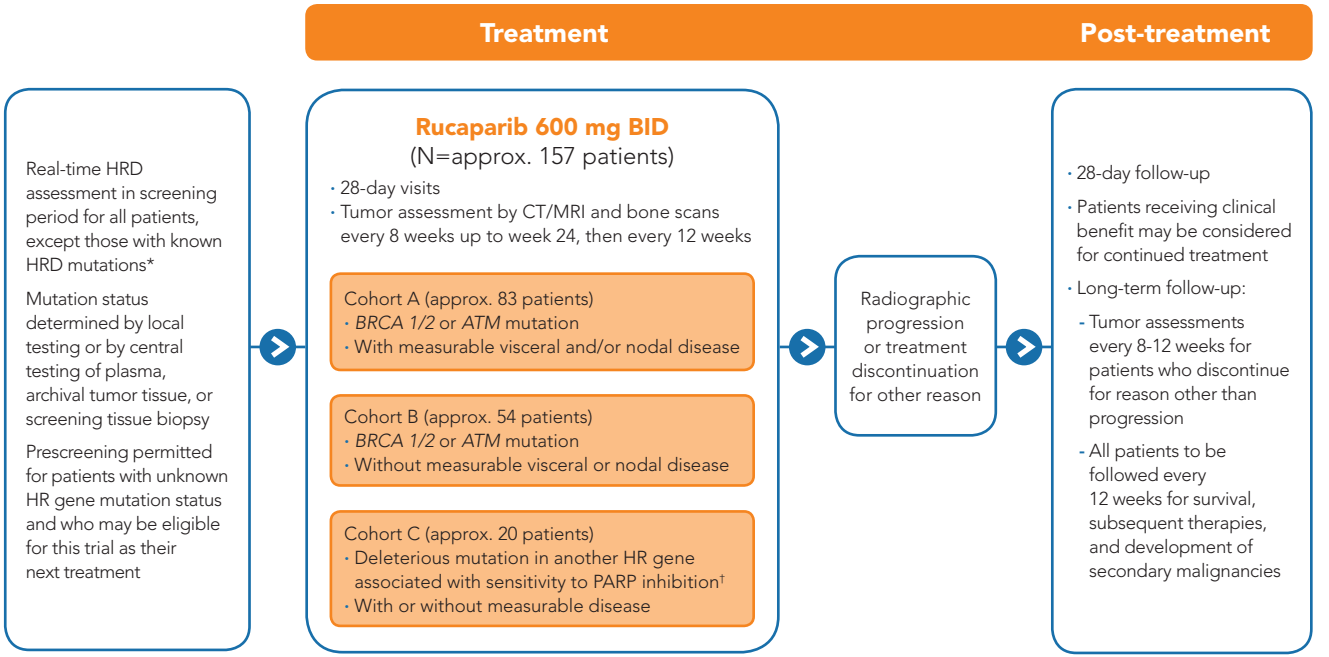
Rucaparib is an oral, small-molecule PARP inhibitor

Please visit www.ClinicalTrials.gov for more information on this trial (NCT02952534)

TRITON2 is sponsored by Clovis Oncology, Inc., Boulder, CO, USA

Rucaparib has not been demonstrated to be safe or effective, nor has it been approved by any regulatory authority, including the US Food and Drug Administration (FDA), for use in this disease indication.

TRITON2 Trial Schema



*Patients with known HRD mutations are required to submit archival tumor tissue, if available; however, enrollment is not contingent on analysis.
†*BARD1, BRIP1, CDK12, CHEK2, FANCA, NBN, PALB2, RAD51, RAD51B, RAD51C, RAD51D,* and *RAD54L.*
ATM=ataxia telangiectasia mutated; BID=twice daily; *BRCA 1/2*=breast cancer susceptibility gene 1/2; HR=homologous recombination; HRD=homologous recombination deficiency; PARP=poly (ADP-ribose) polymerase.

Study Endpoints

Primary Endpoint:

· Response rate:
- Cohort A: centrally assessed objective response rate (ORR) by RECIST v1.1
- Cohort B: locally assessed prostate-specific antigen (PSA) response (decrease of ≥50%)
- Cohort C: centrally assessed ORR by modified RECIST v1.1 if measurable visceral and/or nodal disease present **OR** locally assessed PSA response if visceral and/or nodal disease absent

Secondary Endpoints:

· Duration of response (DOR)
· Radiographic progression-free survival (rPFS)
· Overall survival (OS)
· Clinical benefit rate (CBR)
· PSA response of ≥50% and ≥90% (all patients)
· Time to PSA progression
· Steady-state pharmacokinetics (PK) of rucaparib
· Safety and tolerability

Key Eligibility Criteria

· Confirmed adenocarcinoma or poorly differentiated carcinoma of the prostate
· Surgically or medically castrated with testosterone levels of ≤50 ng/dL (1.73 nM)
· Disease progression after prior therapy for mCRPC, including
- Treatment with 1-2 prior next-generation androgen receptor targeted therapies, **and**
- Treatment with 1 prior taxane-based chemotherapy
· No prior treatment with any PARP inhibitor, mitoxantrone, cyclophosphamide, or any platinum-based chemotherapy
· No symptomatic and/or untreated central nervous system (CNS) metastases or active secondary malignancy

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TRIAL OF RUCAPARIB IN PROSTATE INDICATIONS