TRITON3

A Phase 3, Multicenter, Randomized, Open-Label Study of Rucaparib versus Physician's Choice of Therapy in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Associated with Homologous Recombination Deficiency (HRD)

RUCAPARIB

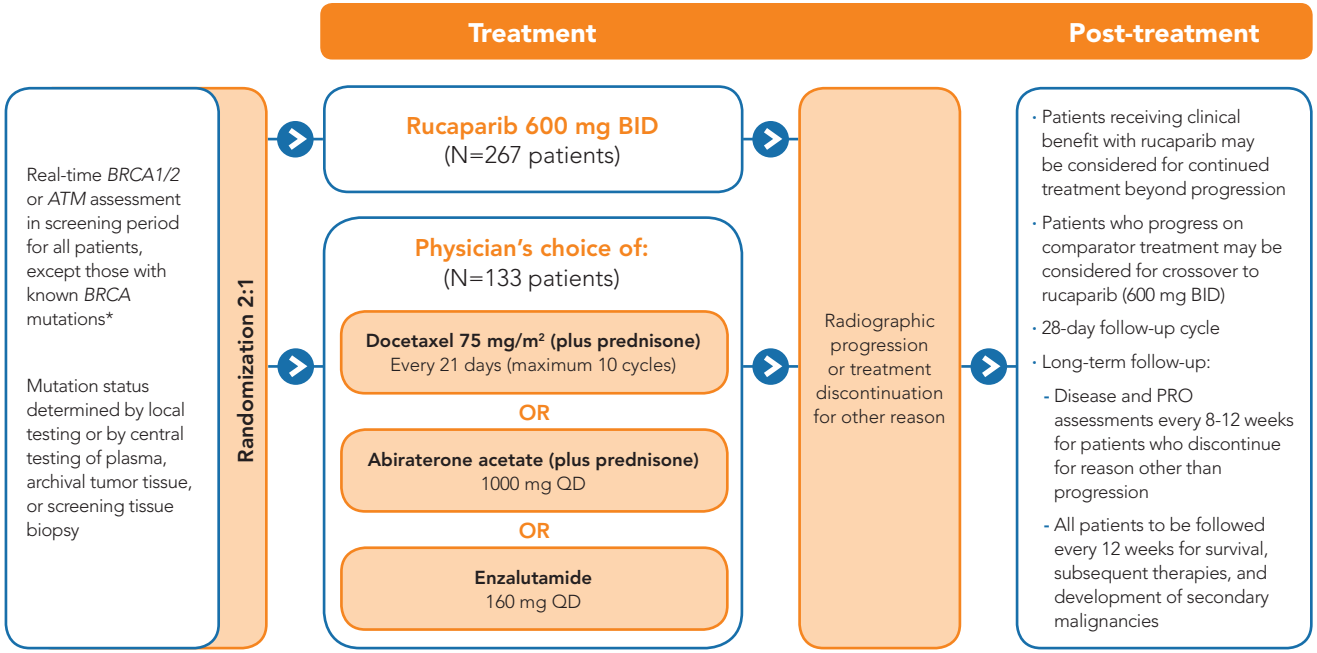
Rucaparib is an oral small-molecule PARP inhibitor

Please visit www.ClinicalTrials.gov for more information on this trial (NCT02975934)

TRITON3 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.

TRITON3 Trial Schema



*Patients with known *BRCA1/2* or *ATM* mutations should also submit archival tumor tissue, if available; biopsy of visceral/nodal metastasis preferred.

ATM=ataxia-telangiectasia mutated; BID=twice daily; BRCA=breast cancer susceptibility gene; HRD=homologous recombination deficiency; PARP=poly (ADP-ribose) polymerase; PRO=patient-reported outcomes; QD=once daily.

Study Endpoints

Primary Endpoint:

- Radiographic progression-free survival (rPFS)

Secondary Endpoints:

- Objective response rate (ORR) by RECIST v1.1 in patients with measurable nodal/visceral disease
- Duration of Response (DOR) by RECIST v1.1 in patients with measurable nodal/visceral disease
- Overall survival (OS)
- Clinical benefit rate (CBR)
- PSA response of ≥50% and ≥90% (all patients)
- Time to PSA progression (TTP)
- Patient-reported outcomes (PRO)
- 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 prior next-generation androgen receptor targeted therapy
- *BRCA1/2* or *ATM* gene mutation per local or central laboratory testing
  - 300 patients carrying a *BRCA1/2* gene mutation and 100 patients carrying an *ATM* gene mutation will be enrolled across all treatment arms
- No prior treatment with any PARP inhibitor or with chemotherapy (such as docetaxel, mitoxantrone, cyclophosphamide, platinum-based agents) for mCRPC
- No symptomatic and/or untreated central nervous system (CNS) metastases or active secondary malignancy

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TRIAL OF RUCAPARIB IN PROSTATE INDICATIONS