ARIEL4

A Phase 3, Multicenter, Randomized Study of Rucaparib vs Chemotherapy in Patients With Relapsed *BRCA*-Mutant, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

RUCAPARIB

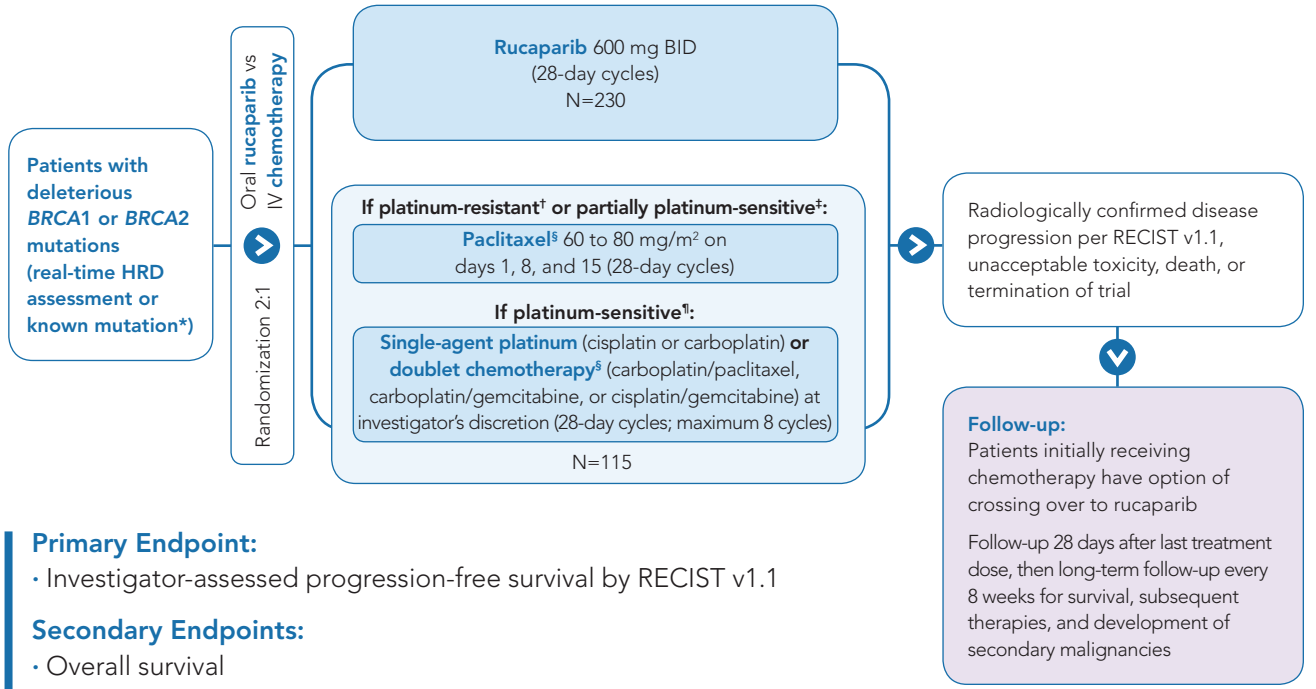
Rucaparib is an oral, small-molecule PARP inhibitor.

Please visit ClinicalTrials.gov for more information on this trial (NCT02855944).

ARIEL4 is sponsored by Clovis Oncology, Inc; Boulder, CO, USA

Rucaparib has received accelerated approval in the United States as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. The clinical benefit of rucaparib is being further studied in this confirmatory trial. Outside of the United States, rucaparib is still an investigational agent only and has not been approved by any other global agency that regulates medicines.

ARIEL4 Trial Schema



Primary Endpoint:

- Investigator-assessed progression-free survival by RECIST v1.1

Secondary Endpoints:

- Overall survival
- Objective Response Rate by RECIST v1.1 and RECIST v1.1 + CA-125
- Duration of Response
- Patient-reported outcomes by EORTC QLQ-C30 and QLQ-OV28
- Safety

*Patients with known *BRCA* mutations, based on local results, must also submit tumor tissue; however, enrollment is not contingent on prior analysis.
†Progressed ≥1 to <6 months after last dose of platinum.
‡Progressed ≥6 to <12 months after last dose of platinum.
§Administered per local standard of care and regulations.
¶Progressed ≥12 months after last dose of platinum.

BID=twice daily; *BRCA*1/2-breast cancer susceptibility gene 1/2; CA-125=cancer antigen 125; EORTC=European Organisation for Research and Treatment of Cancer; HRD=homologous recombinant deficiency; PARP=poly (ADP-ribose) polymerase; QLQ=Quality of Life Questionnaire; RECIST=Response Evaluation Criteria in Solid Tumors.

Key Eligibility Criteria:

- Histologically confirmed diagnosis of high-grade serous or Grade 2 or Grade 3 endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Deleterious *BRCA*1 or *BRCA*2 mutation as confirmed by central laboratory HRD test
  - Adequate screening and/or archival (formalin-fixed, paraffin-embedded) tissue available for analysis
- ≥2 prior chemotherapy regimens
- Treatment-free interval ≥6 months after first chemotherapy regimen
- Relapsed or progressive disease as confirmed by radiologic assessment
- No prior treatment with any PARP inhibitor or single-agent paclitaxel for platinum-resistant disease
- No platinum-refractory disease, ie, progression by radiological assessment ≤4 weeks after completing treatment with most recent platinum-based therapy

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Assessment of Rucaparib In ovarian cancEr: phase 3 triaL

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