For additional information on the ARIEL2 (NCT#01891344) clinical trial, visit: www.arielstudy.com

For more information about this or other clinical trials, visit: www.clinicaltrials.gov

If you have questions regarding the ARIEL2 trial, please discuss them with your physician or call: 1-855-262-3040 or email: clovistrials@emergingmed.com

Study Overview

The ARIEL2 (NCT#01891344) is a Phase 2 trial designed to define efficacy, safety, and a diagnostic marker that correlates with positive response to rucaparib. ARIEL2 will explore the effects of rucaparib in women with high-grade ovarian, fallopian tube, or primary peritoneal cancer. Up to 300 participants will be tested for the presence of BRCA1 and BRCA2 mutations as well as other biomarkers that may be important. In this study, all participants will receive rucaparib until their disease worsens or until the participant withdraws from the study. If you qualify for the rucaparib biomarker trial, you will receive the following at no cost: study-related physical exams, lab tests, BRCA and other biomarker results, and the study drug (rucaparib). Rucaparib is an investigational drug, which means it is still being tested in humans and has not been approved by the US Food and Drug Administration (FDA). The study is being sponsored by Clovis Oncology.

Eligibility

• Ages eligible: 18 years or older
• Genders eligible for study: female only
• Accepts healthy volunteers: no

Inclusion Criteria

• Confirmed diagnosis of high-grade serous or endometrioid ovarian, fallopian tube, or primary peritoneal cancer
• Documented radiological relapse
• Received ≥3 prior chemotherapy regimens
• Have biopsiable and measurable disease

Exclusion Criteria

• History of prior cancers except for those that have been curatively treated, with no evidence of cancer currently (provided all chemotherapy was completed >6 months prior and/or bone marrow transplant >2 years prior to first dose of rucaparib)
• Prior treatment with any PARP inhibitor
• Symptomatic and/or untreated central nervous system metastases
• Pre-existing duodenal stent and/or any gastrointestinal disorder or defect that would interfere with absorption of rucaparib
• Hospitalization for bowel obstruction within 3 months prior to enrollment
Key Questions to Ask Your Oncologist

- Is the rucaparib study a potential option for me?
- Do I have high-grade ovarian, fallopian tube, or primary peritoneal cancer?
- Do I have sufficient tissue archived from a tumor biopsy?
- Am I eligible for a biopsy procedure?
- If I meet the enrollment criteria, what are the potential risks and benefits of participation?

Additional Questions to Ask Your Oncologist

- How will participation in the rucaparib trial compare to my current and prior treatments?
- How long will I receive study drug while on the trial?
- What are the side effects of rucaparib?
- What is a placebo?
- What are the chances I receive rucaparib versus the chances I receive placebo?
- Will I get to know and keep the results from my DNA diagnostic test? When will I receive the test results?
- Who will monitor my care during the trial?
- Who reviews the information during the clinical trial?
- What are my responsibilities if I participate in this trial?
- How often will I need to visit the physician’s office?
- What is the long-term follow-up care?
- Can I take my regular medication while participating in the trial?
- Will my health insurance cover any costs? What questions should I ask my provider to understand what costs I may be responsible for?
- Will I find out the trial results if I participate?
- Can I leave the clinical trial at any time if I want?
- Who should I contact in case of an emergency?
- Is there anything I am prohibited from doing while on the rucaparib trial?