**NCT01540565**  
**A Phase II Evaluation of the Poly (ADP-Ribose) Polymerase (PARP)-1 and -2 Inhibitor Veliparib (ABT-888) (NSC#737664) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Patients Who Carry a Germline BRCA1 or BRCA2 Mutation**

<table>
<thead>
<tr>
<th><strong>Phase</strong></th>
<th>II</th>
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<tr>
<td><strong>Drug Class</strong></td>
<td>PARP inhibitor</td>
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<tr>
<td><strong>Drug Name</strong></td>
<td>Veliparib</td>
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<tr>
<td><strong>Alternate Drug Names</strong></td>
<td>ABT888</td>
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<td><strong>Eligible Participant</strong></td>
<td>Germline BRCA1/2 mutated ovarian cancer; ≤3 prior therapies; no prior PARP inhibitor treatment</td>
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<td><strong>Patients Enrolled</strong></td>
<td>50</td>
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<td><strong>Therapy Setting</strong></td>
<td>Recurrence</td>
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<td><strong>Study Design</strong></td>
<td>Open Label, Non-Randomized</td>
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<td><strong>Endpoints</strong></td>
<td><strong>PFS; ORR</strong> evaluated per RECIST</td>
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<td><strong>Biomarkers</strong></td>
<td>BRCA1/2 germline mutations</td>
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**Efficacy**

- **ORR**: 26% (16%-38%; 2 CR, 11 PR)
- **PFS**: 8.18 months
- **Exploratory sub-group analysis:**
  - **ORR** (platinum-resistant): 20% (n=30)
  - **ORR** (platinum-sensitive): 35% (n=20)

**Clinically Significant Adverse Events**

- Serious AE: none
- Grade 3-4 AE: fatigue (6%), and nausea (4%)

**Conclusion**

Antitumor activity in platinum-resistant and platinum-sensitive BRCA1/2-mutated cancer

**Reference**

Legend

Therapy Setting
First-line – Therapy given to patients on initial diagnosis of disease as the first, best treatment option.
Maintenance – Therapy given to patients to help keep cancer from coming back after it has responded to therapy.
Recurrence – Therapy given to patients in whom disease has returned after prior therapy.

Study Design
Randomized -- A study in which participants are assigned by chance to the separate study groups.
Non-randomized -- A study in which participants are NOT assigned by chance to the separate study groups.

Efficacy Endpoints
PFS: Progression-Free Survival—length of time during and after treatment during which the cancer does not get worse (usually reported as the time when the cancer for half—or median-- of the people in the treatment group gets worse).
OS: Overall Survival—length of time from the start of treatment that patients are still alive (usually reported as the time when half--or median-- of the people in the treatment group are still alive).
CR: Complete Response -- The disappearance of all signs of cancer in response to treatment.
SD: Stable Disease Response -- Cancer that is neither decreasing nor increasing in extent or severity.
ORR: Objective Response Rate -- Sum of complete and partial tumor responses to treatment, divided by the number of patients evaluated.
DCR: Disease Control Rate -- Sum of complete, partial and stable disease tumor responses to treatment, divided by the number of patients evaluated.
HR: Hazard Ratio--measures survival in the treatment group compared to the control group. An HR = 1 means that there is no difference in survival between the groups.  An HR < 1 means that the treatment group has a lower risk of death compared to the control group.  Range in parentheses is 95% Confidence Interval (CI).
RECIST: Response Evaluation Criteria in Solid Tumors -- Set of rules, based on measurements of the change in tumor size that define when cancer patients improve, stabilize, or worsen during a treatment regimen.
CA125: GCIG CA125 Criteria -- Set of rules, based on measurements of the CA125 biomarker level that define when cancer patients improve, stabilize, or worsen during a treatment regimen

Clinically Significant Adverse Events (Based on National Cancer Institute--Common Terminology Criteria for Adverse Events (CTCAE))
AE: Adverse events-- any undesirable experience associated with the use of a drug
SAE: Serious adverse events – untoward event associated with drug treatment e.g., death, life-threatening, requiring of hospitalization, persistent or significant incapacity; usually graded from 1-5.