<table>
<thead>
<tr>
<th>NCT00494442</th>
<th>Study to assess the efficacy and safety of a PARP inhibitor for the treatment of BRCA-positive advanced ovarian cancer (ICEBERG 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>II</td>
</tr>
<tr>
<td><strong>Drug Class</strong></td>
<td>PARP Inhibitor</td>
</tr>
<tr>
<td><strong>Drug Name</strong></td>
<td>Olaparib</td>
</tr>
<tr>
<td><strong>Alternate Drug Names</strong></td>
<td>AZD2281, KU-0059436, Lynparza</td>
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<tr>
<td><strong>Eligible Participant</strong></td>
<td>BRCA1/2-mutated ovarian cancer with measurable disease after ≥1 prior chemotherapy</td>
</tr>
<tr>
<td><strong>Patients Enrolled</strong></td>
<td>57</td>
</tr>
<tr>
<td><strong>Therapy Setting</strong></td>
<td>Recurrence</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Open Label, Non-Randomized</td>
</tr>
<tr>
<td><strong>Endpoints</strong></td>
<td>ORR evaluated per RECIST</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td>BRCA1/2 germline mutations</td>
</tr>
</tbody>
</table>
| **Efficacy** | **ORR**: 33% (20-51%) 400 mg BID dose  
**ORR**: 13% (4-31%) 100 mg BID dose                                                                                 |
| **Clinically Significant Adverse Events** | Serious AE: 400 mg vs 100 mg: none  
Grade 3-4 AE: 400 mg vs 100mg: anemia (3% vs 0), nausea (6% vs 8%), and fatigue (3% vs 0) |
| **Conclusion** | Anti-tumor activity shown in heavily pre-treated patient population                                                |
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).
RR: Response Rate—percentage of patients whose cancer shrinks or disappears after treatment.
PR: Partial Response -- Number of partial tumor responses to treatment, divided by the number of patients evaluated.
CR: Complete Response -- Number of complete tumor responses to treatment, divided by the number of patients evaluated.
ORR: Objective Response Rate -- Sum of complete and partial 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.