<table>
<thead>
<tr>
<th>NCT01696032</th>
<th><strong>A Randomized, Controlled, Open-Label, Phase 2 Trial of SGI-110 and Carboplatin in Subjects With Platinum-Resistant Recurrent Ovarian Cancer</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>II</td>
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<tr>
<td><strong>Drug Class</strong></td>
<td>Chromatin Structure/Gene Expression Regulators: Hypomethylating agents (HMA)</td>
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<tr>
<td><strong>Drug Name</strong></td>
<td>Guadecitabine</td>
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<tr>
<td><strong>Alternate Drug Names</strong></td>
<td>SGI-110</td>
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<tr>
<td><strong>Eligible Participant</strong></td>
<td>Recurrent Platinum-resistant, measurable disease, no limit on prior therapies</td>
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<tr>
<td><strong>Patients Enrolled</strong></td>
<td>100</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><strong>ORR</strong> by RECIST; <strong>DCR</strong>; <strong>PFS</strong>; <strong>OS</strong></td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td>none</td>
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| **Efficacy** | Carbotaxol + Guadecitabine (GC) vs Treatment of Choice (Taxol, Doxil, Topotecan or Gemzar)(TC):  
  **ORR**: 16% (1CR, 7PR, n=51) vs 6% (3 PR, n=49)  
  **DCR**: 37% (1CR, 7PR, 11 SD) vs 27% (3PR, 10SD)  
  **PFS**: 4.1 months vs 2.3 months (HR: 0.74)  
  **OS**: 11.0 months vs 7.4 months (HR: 0.88) |
| **Clinically Significant Adverse Events** | Serious AE: none  
  Grade 3-4 AE: GC vs TC: neutropenia (67% vs 18%), leukopenia (25% vs 4%), anemia (14% vs 14%) |
| **Conclusion** | Encouraging activity of guadecitabine in combination with carbotaxol in heavily pretreated patients                               |
| **Reference** | Matulonis U et al. *Epigenetic resensitization to platinum in recurrent, platinum-resistant ovarian cancer (OC) using guadecitabine (SGI-110), a novel hypomethylating agent (HMA): Results of a randomized phase II study*.  
  J Clin Oncol 34 (2016) (suppl; abstr 5547)  
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.