<table>
<thead>
<tr>
<th>NCT01375842</th>
<th>A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of Atezolizumab (MPDL3280A) Administered Intravenously as a Single Agent to Patients With Locally Advanced or Metastatic Solid Tumors or Hematologic Malignancies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>Ia</td>
</tr>
<tr>
<td><strong>Drug Class</strong></td>
<td>Immunotherapy: Immune Checkpoint Inhibitors/PD-L1</td>
</tr>
<tr>
<td><strong>Drug Name</strong></td>
<td>Atezolizumab</td>
</tr>
<tr>
<td><strong>Alternate Drug Names</strong></td>
<td>MPDL3280A, Tecentriq™</td>
</tr>
<tr>
<td><strong>Eligible Participant</strong></td>
<td>Metastatic or Locally Advanced Solid Tumors</td>
</tr>
<tr>
<td><strong>Patients Enrolled</strong></td>
<td>661 (12 ovarian)</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>Overall Response (ORR) evaluated per RECIST; PFS; OS</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td>PD-L1 status by IHC</td>
</tr>
</tbody>
</table>
| **Efficacy** | **ORR**: 22% (2 PR, n=9)  
**PFS**: 2.9 months (1.3-5.5 months)  
**OS**: 11.3 months (5.5-27.7 months)  
**Exploratory subgroup analysis: response vs PD-L1 expression level:**  
Responders were PD-L1 IC2/3 (PD-L1 positive) and had low CA125 baseline levels |
| **Clinically Significant Adverse Events** | Serious AE: none  
Grade 3-4 AE: autoimmune hepatitis (1/12), maculopapular rash (1/12) |
| **Conclusion** | Encouraging activity with acceptable safety profile |
| **Reference** | Infante, JR et al. Safety, clinical activity and biomarkers of atezolizumab (atezo) in advanced ovarian cancer (OC)  
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.