**Aims of the Study**

- To evaluate safety.
- To evaluate antitumor activity in terms of response duration, progression free survival and overall survival.
- To investigate the pharmacokinetics of AP5346 in this population.

**Study Design**

This is an open label, single arm, phase I/II trial with AP5346 administered as a 2-hour intravenous infusion to AOC patients on day 1 of a 2-week or 3-week cycle. The trial was designed to identify the maximum tolerated dose (MTD) of AP5346 after 3 cycles. If at least 2 of 6 evaluable pts have toxicity, DL 2=RD. If >2/6 have toxicity, STOP dose escalation.

**Patient Characteristics**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Median</th>
<th>Range</th>
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<tbody>
<tr>
<td></td>
<td>60</td>
<td>30-70</td>
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**Eligibility Criteria**

- **Platinum-sensitive** patients with platinum-sensitive ovarian cancer.
- **Platinum-resistant** patients with platinum-resistant ovarian cancer.
- **Platinum-refractory** patients with platinum-refractory ovarian cancer.
- **Platinum-ineligible** patients with platinum-refractory ovarian cancer.
- **Performance Status (ECOG)**
  - 0
  - 1

**Primary Objective**

- Evaluate antitumor activity (RECIST and ECOG criteria for CA125 response) of single agent AP5346 as 3rd or 4th line chemotherapy in AOC patients, compared with historical and available non-platinum based regimens in AOC.

**Secondary Objectives**

- To establish a maximum tolerated dose (MTD) of AP5346 after 3 cycles.
- To establish a response rate of single agent AP5346 in the platinum-resistant, platinum-refractory, and platinum-ineligible patient populations.
- To determine the optimal dose and schedule for AP5346 in the platinum-resistant, platinum-refractory, and platinum-ineligible patient populations.

**Safety**

- Monitor for adverse drug reactions (injection site reactions, nausea, vomiting, constipation, diarrhea, fatigue, anorexia, alopecia, and pyrexia) that require appropriate intervention.

**Efficacy**

- Evaluate response to therapy using RECIST and ECOG criteria for CA125 response.

**Conclusion**

- Despite the heavily pre-treated nature and clinical resistance to platinum drugs of the study population, population, selected events of activity were seen in several patients at higher dose levels. Furthermore, the level of activity observed in the platinum-resistant population was encouraging.

**References**