<table>
<thead>
<tr>
<th>NCT00532194</th>
<th>A Randomised, Placebo-controlled, Trial of Concurrent Cediranib [AZD2171] (With Platinum-based Chemotherapy) and Concurrent and Maintenance Cediranib in Women With Platinum-sensitive Relapsed Ovarian Cancer</th>
</tr>
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<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>III</td>
</tr>
<tr>
<td><strong>Drug Class</strong></td>
<td>Angiogenesis Inhibitors: VEGFR</td>
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<tr>
<td><strong>Drug Name</strong></td>
<td>Cediranib</td>
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<td><strong>Alternate Drug Names</strong></td>
<td>AZD2171, Recentin</td>
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<td><strong>Eligible Participant</strong></td>
<td>Platinum-sensitive cancer at first relapse</td>
</tr>
<tr>
<td><strong>Patients Enrolled</strong></td>
<td>456</td>
</tr>
<tr>
<td><strong>Therapy Setting</strong></td>
<td>Recurrence; Maintenance</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Double Blind, Randomized</td>
</tr>
<tr>
<td><strong>Endpoints</strong></td>
<td>PFS; OS</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td>None</td>
</tr>
</tbody>
</table>
| **Efficacy** | **PFS**: 11.1 months (ced-throughout + carbo-tax (CT)) vs 9.9 months (ced-initiation + CT) vs 8.7 months (CT)  
**HR**: 0.56 (0.44–0.72, p<0.0001) for ced-throughout + CT vs CT  
**OS**: 27.3 months (ced-throughout + carbo-tax (CT)) vs 26.6 months (ced-initiation + CT) vs 19.9 months (CT)  
**HR**: 0.85 (0.66–1.10, p=0.21) for ced-throughout + CT vs CT |
| **Clinically Significant Adverse Events** | Serious AE: pneumonia (1 pt, cedirinib concurrent; 1 pt in control), somnolence (1pt in control), GI perforation (1 pt concurrent), cardiac ischaemia (1 pt concurrent), pancreatitis and hypoxia (1 pt, ced throughout)  
Grade 3-4 AE for ced+ CT vs. CT: fatigue (16% vs. 8%); hypertension (12% vs. 3%), diarrhea (10% vs. 2%), neutropenia (26% vs. 23%)—all reduced during maintenance phase |
| **Conclusion** | Improved PFS with addition of cediranib                                                                                                                                                             |
Lederman JA et al. *Overall survival results of ICON6: A trial of chemotherapy and cediranib in relapsed ovarian cancer*. J Clin Oncol 35, 2017 (suppl; abstr 5506)  
[http://abstracts.asco.org/199/AbstView_199_191817.html](http://abstracts.asco.org/199/AbstView_199_191817.html) |
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.