Oral Plenary
Plenary I
IGCS20_1256

1 AVELUMAB IN COMBINATION WITH AND/OR FOLLOWING CHEMOTHERAPY VS CHEMOTHERAPY IN TREATMENT-NAIVE PATIENTS WITH OVARIAN CANCER: BIOMARKER ANALYSES FROM THE PHASE 3 JAVELIN OVARIAN 100 TRIAL

1.43 [1.051, 1.946], respectively). The trial was terminated –

Abstract 1 Table 1

<table>
<thead>
<tr>
<th>PFS in biomarker-defined subgroups</th>
<th>CTx+9 Ave (N=582)</th>
<th>CTx+9 Ave/9 Ave (N=660)</th>
<th>CTx+9 Bit (N=853)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDL1+ subgroup</td>
<td>N=138</td>
<td>N=160</td>
<td>N=169</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>1.23 (0.700, 1.924)</td>
<td>0.98 (0.618, 1.541)</td>
<td>–</td>
</tr>
<tr>
<td>PD-L1- subgroup</td>
<td>N=112</td>
<td>N=103</td>
<td>N=111</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>16.8 (12.8, NE)</td>
<td>13.9 (12.5, 18.1)</td>
<td>13.6 (12.6, NE)</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>1.02 (0.607, 1.794)</td>
<td>1.06 (0.815, 2.269)</td>
<td>–</td>
</tr>
<tr>
<td>CD8- subgroup</td>
<td>N=107</td>
<td>N=107</td>
<td>N=118</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>14.3 (12.8, NE)</td>
<td>15.0 (15.0, 21.2)</td>
<td>15.0 (14.6, NE)</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>1.64 (0.946, 2.850)</td>
<td>1.25 (0.795, 2.218)</td>
<td>–</td>
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<tr>
<td>CD8- subgroup</td>
<td>N=143</td>
<td>N=143</td>
<td>N=139</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>15.6 (15.2, NE)</td>
<td>15.0 (13.2, NE)</td>
<td>15.0 (14.6, NE)</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>0.94 (0.594, 1.498)</td>
<td>0.94 (0.708, 1.740)</td>
<td>–</td>
</tr>
<tr>
<td>BRCA1/2-mutated subgroup</td>
<td>N=51</td>
<td>N=31</td>
<td>N=50</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>(18.0, NE)</td>
<td>(16.4, NE)</td>
<td>(15.3, NE)</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>1.98 (0.647, 3.315)</td>
<td>2.51 (0.970, 11.09)</td>
<td>–</td>
</tr>
<tr>
<td>BRCA1/2-wilde-type subgroup</td>
<td>N=277</td>
<td>N=289</td>
<td>N=281</td>
</tr>
<tr>
<td>Median, months (95% CI)</td>
<td>15.7 (12.9, NE)</td>
<td>18.1 (16.4, NE)</td>
<td>17.5 (17.3, NE)</td>
</tr>
<tr>
<td>HR vs control (95% CI)</td>
<td>1.32 (0.956, 1.833)</td>
<td>1.14 (0.825, 1.593)</td>
<td>–</td>
</tr>
</tbody>
</table>

HR, hazard ratio; NE, not estimable

Because the trial was terminated at the interim analysis, the duration of available follow-up for PFS was not long enough for the median duratons to be reached when prespecified futility boundaries were crossed at the interim analysis, and study treatment was subsequently discontinued. Here we report biomarker analyses.

Methods Women with stage III-IV EOC (post debulking/cytoreductive surgery or candidates for neoadjuvant chemotherapy) were randomized 1:1:1 to receive carboplatin/paclitaxel chemotherapy (6 cycles) followed by avelumab every 2 weeks as maintenance (CTX=Ave), chemotherapy + avelumab (10 mg/kg every 3 weeks) followed by avelumab every 2 weeks as maintenance (CTX+Ave=Ave), or chemotherapy followed by observation (CTX=O; control arm). The primary endpoint was PFS by blinded independent central review per RECIST version 1.1. Pretreatment tumor tissue was analyzed by immuno-histochemistry (CD8 and PD-L1) and next-generation DNA and RNA sequencing.

Results 998 patients were randomized. Subgroup analyses based on PD-L1, CD8, and germline BRCA1/2 status did not identify subsets with clear PFS benefit in either avelumab arm vs control (table 1). Whole-exome and RNA sequencing analyses will be presented.

Conclusions In the JAVELIN Ovarian 100 trial, PD-L1, CD8, and germline BRCA1/2 status did not predict differential clinical benefit with the addition of avelumab to chemotherapy in treatment-naive patients with EOC.

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2 EFFICACY AND SAFETY OF LENVATINIB PLUS PEMBROLIZUMAB IN PATIENTS WITH PREVIOUSLY TREATED OVARIAN CANCER IN THE MULTICOHORT PHASE 2 LEAP-005 STUDY

1 González-Martín*, 2H Chung, 3E Saada-Bouzid, 4E Yanez, 5H Senellart, 6PA Cassier, 7B Basu, 8R Ghoti, 9P Kubiat, 10A Smith, 11K Norwood, 12L Lwin. 1Clínica Universidad de Navarra, Spain; 2Yonsei Cancer Center, Yonsei University College of Medicine, South Korea; 3Department of Medical Oncology, Centre de Lutte Contre le Cancer Antoine Lacassagne, France; 4Oncology-Hematology Unit, Department of Internal Medicine, School of Medicine, Universidad de la Frontera, Chile; 5Institut de Cancérologie de l'Ouest, Centre René Gauducheau ICO, France; 6Department of Medical Oncology, Centre Léon Bérard, France; 7Department of Oncology, University of Cambridge, UK; 8Merk and Co., Inc., USA; 9Eisai Inc., USA; 10Esai Ltd., UK; 11Royal Brisbane and Women's Hospital, Australia

Introduction Lenvatinib, an antiangiogenic multiple receptor tyrosine kinase inhibitor, plus pembrolizumab, a programmed death-1 immune checkpoint inhibitor, demonstrated promising clinical benefit in a previous phase Ib/II trial across several cancer types (ClinicalTrials.gov, NCT02501096). We assessed clinical outcomes with lenvatinib plus pembrolizumab in patients with ovarian cancer in the ongoing, open-label, multi-cohort, phase 2 LEAP-005 study (ClinicalTrials.gov, NCT037979326).

Methods Female patients aged ≥18 years with histologically/ cytotologically confirmed, metastatic/unresectable ovarian cancer, measurable disease per RECIST v1.1, ECOG performance status 0/1, and 3 prior lines of therapy were enrolled. Patients received lenvatinib 20 mg daily plus pembrolizumab 200 mg every 3 weeks for 35 cycles, or until confirmed disease progression or unacceptable toxicity. Primary endpoints were objective response rate (ORR; response assessed every 9 weeks for 54 weeks, then every 12 weeks, by blinded independent