

## 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

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**Introduction** In the JAVELIN Ovarian 100 trial (NCT02718417), avelumab (anti-PD-L1) in combination with chemotherapy or as maintenance did not improve progression-free survival (PFS) vs chemotherapy followed by observation in treatment-naive patients with epithelial ovarian cancer (EOC; hazard ratios [95% CI] were 1.14 [0.832, 1.565] and 1.43 [1.051, 1.946], respectively). The trial was terminated

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 immunohistochemistry (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.

## IGCS20\_1255

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

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**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, NCT03797326).

**Methods** Female patients aged ≥18 years with histologically/cytologically 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

Abstract 1 Table 1

| PFS in biomarker-defined subgroups |                    |                        |                  |
|------------------------------------|--------------------|------------------------|------------------|
|                                    | CTx→Ave<br>(N=332) | CTx+Ave→Ave<br>(N=331) | CTx→O<br>(N=335) |
| <b>PD-L1+ subgroup</b>             | <b>N=158</b>       | <b>N=160</b>           | <b>N=169</b>     |
| Median, months                     | NE                 | NE                     | NE               |
| (95% CI)                           | (12.9, NE)         | (16.4, NE)             | (17.5, NE)       |
| HR vs control                      | 1.23               | 0.98                   | -                |
| (95% CI)                           | (0.790, 1.924)     | (0.618, 1.541)         | -                |
| <b>PD-L1- subgroup</b>             | <b>N=112</b>       | <b>N=103</b>           | <b>N=111</b>     |
| Median, months                     | 16.8               | 13.9                   | NE               |
| (95% CI)                           | (12.8, NE)         | (12.5, 18.1)           | (12.6, NE)       |
| HR vs control                      | 1.02               | 1.36                   | -                |
| (95% CI)                           | (0.607, 1.704)     | (0.819, 2.269)         | -                |
| <b>CD8+ subgroup</b>               | <b>N=107</b>       | <b>N=107</b>           | <b>N=118</b>     |
| Median, months                     | 14.3               | NE                     | NE               |
| (95% CI)                           | (12.8, NE)         | (15.0, NE)             | (18.2, NE)       |
| HR vs control                      | 1.64               | 1.25                   | -                |
| (95% CI)                           | (0.946, 2.850)     | (0.705, 2.218)         | -                |
| <b>CD8- subgroup</b>               | <b>N=143</b>       | <b>N=143</b>           | <b>N=139</b>     |
| Median, months                     | NE                 | 15.0                   | NE               |
| (95% CI)                           | (15.2, NE)         | (13.2, NE)             | (14.4, NE)       |
| HR vs control                      | 0.94               | 1.11                   | -                |
| (95% CI)                           | (0.594, 1.498)     | (0.708, 1.740)         | -                |
| <b>BRCA1/2-mutated subgroup</b>    | <b>N=31</b>        | <b>N=32</b>            | <b>N=30</b>      |
| Median, months                     | NE                 | NE                     | NE               |
| (95% CI)                           | (18.0, NE)         | (16.4, NE)             | (15.3, NE)       |
| HR vs control                      | 1.98               | 2.51                   | -                |
| (95% CI)                           | (0.470, 8.315)     | (0.570, 11.09)         | -                |
| <b>BRCA1/2-wild-type subgroup</b>  | <b>N=277</b>       | <b>N=289</b>           | <b>N=281</b>     |
| Median, months                     | 15.7               | 18.1                   | NE               |
| (95% CI)                           | (12.9, NE)         | (14.6, NE)             | (17.5, NE)       |
| HR vs control                      | 1.32               | 1.14                   | -                |
| (95% CI)                           | (0.956, 1.835)     | (0.823, 1.593)         | -                |

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 durations to be reached