Oral Plenary

Plenary I

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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-naïve 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-naïve 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

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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, multicohort, 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 (N=332)	CTx+Ave→Ave (N=331)	CTx→O (N=335)
PD-L1+ subgroup	N=158	N=160	N=169
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)	–
PD-L1- subgroup	N=112	N=103	N=111
Median, months	16.8	13.9	13.9
(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)	–
CD8+ subgroup	N=107	N=107	N=118
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)	–
CD8- subgroup	N=143	N=143	N=139
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)	–
BRCA1/2-mutated subgroup	N=31	N=32	N=30
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)	–
BRCA1/2-wild-type subgroup	N=277	N=289	N=281
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