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Oral Plenary

Plenary I

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 central review per RECIST v1.1) and safety. Secondary endpoints included disease control rate, duration of response, and progression-free survival.

Results: 31 patients with ovarian cancer received ≥1 dose of lenvatinib plus pembrolizumab in LEAP-005 (median age 62 years [range 40–76]); median study follow-up was 7.8 months (range, 4.6–12.4) as of April 10, 2020. ORR was 32% (95% CI, 17–51); other efficacy endpoints were also favorable (Table). Treatment-related adverse events occurred in 29 (94%) patients (Table).

Conclusion: Lenvatinib plus pembrolizumab demonstrated encouraging efficacy and manageable safety in patients with heavily pretreated ovarian cancer, including those with prior platinum failure and those with previous bevacizumab exposure.