LEAP-005: Phase II study of lenvatinib (len) plus pembrolizumab (pembro) in patients (pts) with previously treated advanced solid tumours


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Background: Len (antiangiogenic multiple receptor tyrosine kinase inhibitor) + pembro (anti-PD-1 agent) showed promising clinical outcomes across several cancers in early-phase trials and is FDA-approved for pts with previously treated advanced endometrial cancer that is not MSI-H or mismatch repair-deficient who are ineligible for curative surgery/radiation. We report the first results from the phase 2 LEAP-005 study (NCT03797326), which evaluates the efficacy and safety of len + pembro in pts with select previously treated advanced solid tumors.

Methods: This open-label, multicohort study enrolled pts aged ≥18 with one of the following previously treated, histologically/cytologically confirmed advanced tumors: triple-negative breast (TNBC), ovarian, gastric, colorectal (non-MSI-H/mismatch repair-proficient), glioblastoma multiforme (GBM), or biliary tract (BTC; ampulla of Vater excluded). Pts received len 20 mg/d + pembro 200 mg Q3W for 35 cycles or until confirmed PD or unacceptable toxicity. Primary endpoints are ORR by blinded independent central review per RECIST v1.1 or RANO (GBM only), and safety.

Results: 187 pts have been enrolled in LEAP-005. Median study follow-up at Apr 10, 2020 data cutoff was 8.6 (range, 1.9–13.1) mo. Encouraging efficacy was observed across cohorts, and toxicity was manageable (Table). Conclusions: Len + pembro showed promising antitumor activity and manageable toxicity across the previously treated tumor cohorts evaluated in LEAP-005. The study is ongoing; all cohorts will expand to enroll ≥100 pts/colhort.

Clinical trial identification: NCT03797326.

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