

## 726MO

### Outcomes by histology and prior therapy with lenvatinib plus pembrolizumab vs treatment of physician's choice in patients with advanced endometrial cancer (Study 309/KEYNOTE-775)

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## Background

Study 309/KEYNOTE-775 (NCT03517449) is a phase III trial comparing efficacy and safety of lenvatinib (LEN) + pembrolizumab (pembro) vs treatment of physician's choice (TPC) in patients (pts) with previously treated, advanced endometrial cancer (EC). LEN + pembro significantly improved OS and PFS vs TPC in the ITT population (all comers) (HR [95% CI]: OS 0.62 [0.51–0.75]; PFS 0.56 [0.47–0.66]) and in pts with mismatch repair-proficient (pMMR) status (HR [95% CI]: OS 0.68 [0.56–0.84]; PFS 0.60 [0.50–0.72]). We present efficacy outcomes in pts grouped by tumor histology and prior therapy (tx).

## Methods

Eligible pts were ≥18 y with histologically confirmed, previously treated, advanced EC, and a tumor sample for determining MMR status. Pts were randomized to LEN 20 mg PO QD + pembro 200 mg IV Q3W (max. 35 cycles) or TPC (doxorubicin 60 mg/m<sup>2</sup> Q3W [max. cumulative dose, 500 mg/m<sup>2</sup>] or paclitaxel 80 mg/m<sup>2</sup> QW, 3 wks on, 1 wk off). Randomization was stratified by MMR status (proficient vs deficient), then pMMR pts were stratified by ECOG PS (0 vs 1), geographic region, and prior pelvic radiation. Treatment continued until PD, toxicity, or pt withdrawal. Primary endpoints were OS and PFS (RECIST v1.1 by BICR).

## Results

827 pts were enrolled (LEN + pembro, n=411; TPC, n=416). Median (range) time from randomization to data cutoff (Oct 26, 2020) was 16.8 (8.7–28.0) mo. HRs for OS favored LEN + pembro over TPC in most subgroups defined by tumor histology and prior tx (Table). PFS outcomes were consistent with those for OS (to be presented).

## Conclusions

LEN + pembro provided meaningful efficacy improvements in pts with previously treated advanced EC across all histologies (including difficult to treat histologies), and irrespective of prior (neo)adjuvant tx, and platinum-free interval (PFI) from most recent platinum tx. Pts with 1 prior line of platinum had greater benefit than those with ≥1 line, supporting early use of LEN + pembro. Table: 726MO

n	OS HR (95% CI)
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		n	OS HR (95% CI)
			0.78
			(0.57–1.05)0.65
			(0.49–0.84)0.68
			(0.49–0.96)0.68
			(0.48–0.94)0.34
			(0.15–0.78)0.33
			(0.15–0.74)
			0.58
			(0.45–0.73)0.54
			(0.44–0.67)1.10
			(0.73–1.66)0.93
			(0.62–1.38)0.64
			(0.45–0.90)0.67
			(0.48–0.92)0.70
			(0.54–0.91)0.58
			(0.46–0.74)0.65
			(0.51–0.83)0.56
			(0.45–0.70)0.65
			(0.43–0.97)0.65
			(0.44–0.96)

## Clinical trial identification

NCT03517449.

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## Legal entity responsible for the study

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## Disclosure

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