#1121 KEYNOTE-826: FINAL OVERALL SURVIVAL RESULTS FROM A RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY OF PEMBROLIZUMAB + CHEMOTHERAPY VS PLACEBO + CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF PERSISTENT, RECURRENT, OR METASTATIC CERVICAL CANCER

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Introduction/Background The first interim analysis of KEYNOTE-826 (NCT03635567) showed that first-line pembrolizumab (pembro) + chemotherapy (chemo) provided statistically significant and clinically meaningful improvements in OS and PFS vs placebo (pbo) + chemo in patients (pts) with recurrent, persistent, or metastatic cervical cancer across all prespecified populations (PD-L1 combined positive score [CPS] ≥1, all-comer, and CPS ≥10). Here, we present the protocol-specified final OS analysis results of KEYNOTE-826.

Methodology Eligible adults with persistent, recurrent, or metastatic cervical cancer not previously treated with systemic chemo (prior radiosensitizing chemo allowed) and not amenable to curative treatment (surgery or radiation) were randomized 1:1 to pembro 200 mg or placebo Q3W for up to 35 cycles + chemo (paclitaxel 175 mg/m2 + cisplatin 50 mg/m2 or carboplatin AUC 5), ± bev 15 mg/kg. Pts were stratified by metastatic status at diagnosis (yes/no), planned bev use (yes/no), and PD-L1 CPS (< 1, 1 to < 10, or ≥10). Dual primary end points were OS and PFS per RECIST v1.1 assessed by investigator review, each tested sequentially in the PD-L1 CPS ≥1, all-comer, and CPS ≥10 populations.

Results From Nov 2018 to Jan 2020, 617 patients were randomized (pembro + chemo, n = 308 [63.6% with bev]; pbo + chemo, n = 309 [62.5% with bev]); 548 (88.8%) pts had PD-L1 CPS ≥1 and 317 (51.4%) had CPS ≥10. At the Oct 3, 2022 data cutoff, median follow-up was 39.1 mo. Pembro + chemo significantly improved OS and PFS in the CPS ≥1, all-comer, and CPS ≥10 populations (table 1). The pembro + chemo benefit was seen regardless of bev use. Grade ≥3 AE incidence was 82.4% in the pembro + chemo arm and 75.4% in the placebo + chemo arm. The most common grade ≥3 AEs were anemia (30.3% vs 27.8%), neutropenia (12.4% vs 9.7%), and hypertension (10.4% vs 11.7%).

Conclusion The addition of pembro to chemo ± bev significantly reduced the risk of death by 40% in the PD-L1 CPS ≥1 population, by 37% in the all-comer population, and by 42% in the CPS ≥10 population, and had a manageable safety profile. These data are consistent with the earlier results and provide further support for pembro + chemo ± bev as a new standard of care for first-line treatment of persistent, recurrent, or metastatic cervical cancer.

Disclosures .

Abstract #1121 Table 1

	PD-L1 CPS ≥1		All-Comer		PD-L1 CPS ≥10	
	Pembro + Chemo n = 273	Pbo + Chemo n = 275	Pembro + Chemo n = 308	Pbo + Chemo n = 309	Pembro + Chemo n = 158	Pbo + Chemo n = 159
OS, median, mo	28.6	16.5	26.4	16.8	29.6	17.4
24-mo OS rate, %	53.5	39.4	52.1	38.7	54.4	42.5
OS, HR (95% CI)	0.60 (0.49-0.74); $P < 0.0001$		0.63 (0.52-0.77); $P < 0.0001$		0.58 (0.44-0.78); $P < 0.0001$	
PFS, median, mo	10.5	8.2	10.4	8.2	10.4	8.1
12-mo PFS rate, %	45.6	33.7	44.7	33.1	44.7	33.5
PFS, HR (95% CI)	0.58 (0.47-0.71); $P < 0.0001$		0.61 (0.50-0.74); $P < 0.0001$		0.52 (0.40-0.68); $P < 0.0001$	