Oral Abstracts

Opening Ceremony and Plenary 1: Oral Abstract Presentations

O001/#331 EMPOWER-CERVICAL 1/GOG-3016/ENGOT-CX9: RESULTS OF PHASE 3 TRIAL OF CEMIPLIMAB VS INVESTIGATOR'S CHOICE CHEMOTHERAPY IN RECURRENT/METASTATIC CERVICAL CARCINOMA

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Objectives EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 is an open-label, randomized (1:1), multi-center, Phase 3 trial of cemiplimab vs investigator's choice (IC) chemotherapy (chemo) in recurrent/metastatic (R/M) cervical cancer that has progressed after first-line (1L) platinum-based treatment (tx).
Methods Patients (pts) were enrolled regardless of PD-L1 expression; received cemiplimab 350 mg IV Q3W or IC chemo (pemetrexed, vinorelbine, gemcitabine, irinotecan, or topotecan), up to 96 weeks; and were stratified by histology (squamous cell carcinoma [SCC]/adenocarcinoma or adenosquamous [AC]). Primary endpoint was OS, analyzed hierarchically in pts with SCC followed by total population (SCC + AC). Additional endpoints included PFS, ORR, QoL, and safety. Interim analysis was scheduled when 85% events occurred among SCC pts.
Results 608 pts were randomized: median age, 51 years (range, 22–87); 477 SCC, 131 AC; ECOG performance status: 0 (46.5%), 1 (53.5%). Median cemiplimab exposure was 15 weeks (range, 1.4–100.7). At interim analysis, OS (table 1), PFS, ORR in overall and SCC populations, and mean change from baseline QoL in SCC, favored cemiplimab. Most common tx emergent AEs of any grade for cemiplimab vs IC chemo were anemia (25% vs 45%), nausea (18% vs 33%), and vomiting (16% vs 23%). Discontinuation due to AEs occurred in 8% (cemiplimab) and 5% (IC chemo).
Conclusions Cemiplimab significantly improves OS over single agent chemo for pts with R/M cervical cancer after 1L platinum-based tx regardless of histology and despite not having been selected by PD-L1 status. No new safety signals were observed.

Abstract O001/#331 Table 1

	Cemiplimab median OS months (n)	IC chemo median OS months (n)	Hazard ratio for death (95% confidence interval)	*P* value
Total population	12.0 (n=304)	8.5 (n=304)	0.69 (0.56–0.84)	*P*<0.001
SCC population	11.1 (n=239)	8.8 (n=238)	0.73 (0.58–0.91)	*P*=0.003
AC population	13.3 (n=65)	7.0 (n=66)	0.56 (0.36–0.85)	*P*<0.005 (nominal *P* value, not adjusted for multiplicity)

O002/#43 RANDOMIZED PHASE 3 STUDY OF LENVATINIB PLUS PEMBROLIZUMAB FOR ADVANCED ENDOMETRIAL CANCER (AEC): SUBGROUP ANALYSIS OF PATIENTS WITH DNA MISMATCH REPAIR DEFICIENT (DMMR) TUMORS

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Objectives In Study 309/KEYNOTE-775, lenvatinib + pembrolizumab (LEN+pembro) significantly improved PFS, OS, and ORR versus treatment of physician's choice (TPC) in aEC patients with DNA mismatch repair proficient tumors and all-comers following platinum-based therapy. We report results for dMMR aEC patients.
Methods Patients in Study 309/KEYNOTE-775 were randomized 1:1 to lenvatinib 20 mg orally daily + pembrolizumab 200 mg IV Q3W or TPC (doxorubicin 60 mg/m^2 IV Q3W or paclitaxel 80 mg/m^2 IV QW [3 weeks on/1 week off]). Patients had aEC with 1 prior platinum-based chemotherapy regimen (2 if one was given in the neoadjuvant/adjuvant setting). Prespecified efficacy (PFS, OS, and ORR) and safety analyses among dMMR patients are reported. P-values are nominal. Tumors were assessed by blinded independent central review per RECIST v1.1.
Results 130 Patients with dMMR aEC were randomized to LEN+pembro (n=65) or TPC (n=65). Median follow-up was 13.5 months for the LEN+pembro group and 8.8 months for