Oral Abstracts

Opening Ceremony and Plenary 1: Oral Abstract Presentations

0001/#331

EMPOWER-CERVICAL 1/GOG-3016/ENGOT-CX9: RESULTS OF PHASE 3 TRIAL OF CEMIPIMAB 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 adenocarcinoma [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.

0002/#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/m² IV Q3W or paclitaxel 80 mg/m² 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

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	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)

Abstract 0002/#43 Table 1

Table	LEN+pembro (n = 65)	TPC (n = 65)
Median PFS, months (95% CI)	10.7 (5.6, NR)	3.7 (3.1, 4.4)
PFS HR (95% CI)	0.36 (0.23, 0.57)	
P-value	<0.0001	
Median OS, months (95% CI)	NR (NR)	8.6 (5.5, 12.9)
OS HR vs TPC (95% CI)	0.37 (0.22, 0.62)	
P-value	<0.0001	
ORR, % (95% CI)	40.0 (28.0, 52.9)	12.3 (5.5, 22.8)
Difference, % (95% CI)	27.7 (12.9, 41.7)	
P-value	0.0002	
Disease control rate, % (95% CI)	73.8 (61.5, 84.0)	47.7 (35.1, 60.5)
Median duration of response*, months (range)	NR (2.1*, 20.4*)	4.1 (1.9*, 15.6*)
Median time to response*, months (range)	2.9 (1.7, 16.3)	1.9 (1.8, 3.7)

*Duration of response and time to response are based on responders.

*No progressive disease reported at the last disease assessment.

CI, confidence interval; HR, hazard ratio; PFS, progression-free survival; OS, overall survival; NR, not reached; TPC, treatment with physician's choice (doxorubicin or paclitaxel).

the TPC group (data cutoff: October 26, 2020). PFS (median 10.7 vs 3.7 months) and OS (median not reached vs 8.6 months) were longer with LEN+pembro vs TPC. ORR was greater with LEN+pembro (40.0%) vs TPC (12.3%). Additional results are in the Table. Grade ≥ 3 treatment-emergent adverse events occurred in 95% and 73% of patients in the LEN+pembro and TPC groups, respectively.

Conclusions LEN+pembro improved PFS, OS, and ORR vs TPC in patients with dMMR aEC, with a manageable safety profile generally consistent with all-comers and previous studies.

0003/#149

ANTITUMOR ACTIVITY OF DOSTARLIMAB IN PATIENTS WITH ADVANCED OR RECURRENT MISMATCH REPAIR-DEFICIENT OR PROFICIENT-CANCER BY PRIOR THERAPY: RESULTS FROM THE GARNET STUDY

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Objectives Dostarlimab is a humanized programmed death 1 (PD-1) receptor monoclonal antibody that blocks interactions

Abstract 0003/#149 Table 1

Variable	dMMR/MSI-H EC ^a		MMRp EC	
	N	n (%; 95% CI)	N	n (%; 95% CI)
ORR by RECIST v1.1	108	47 (43.5; 34.0–53.4)	142	19 (13.4; 8.3–20.1)
Prior anticancer therapy ^b				
1 prior LOT	69	33 (47.8; 35.6–60.2)	65	9 (13.8; 6.5–24.7)
≥ 2 prior LOTs	39	14 (35.9; 21.2–52.8)	77	10 (13.0; 6.4–22.6)

^aIncludes 2 patients with MSI-H/MMR unknown EC; ^bExcludes hormonal therapy as single-agent treatment.

with PD-1 ligands. GARNET is a phase 1 study assessing anti-tumor activity and safety of dostarlimab monotherapy in patients with advanced solid tumors.

Methods This multicenter, open-label, single-arm study is conducted in 2 parts: dose escalation and expansion. Patients with advanced or recurrent mismatch repair-deficient (dMMR) or microsatellite instability-high (MSI-H) endometrial cancer (EC) or mismatch repair-proficient (MMRp) EC that progressed on or after a platinum regimen received dostarlimab 500 mg intravenously Q3W for 4 cycles, then 1000 mg Q6W until disease progression or discontinuation. Primary endpoints were objective response rate (ORR) and duration of response by BICR using RECIST v1.1. Here we report ORR in dMMR/MSI-H and MMRp EC by prior lines of therapy (LOTs).

Results Efficacy analyses included 108 dMMR/MSI-H and 142 MMRp patients. ORR was 43.5% in dMMR/MSI-H and 13.4% in MMRp. ORR was slightly higher (47.8%) in patients with dMMR/MSI-H with 1 prior LOT but lower (35.9%) in those who received ≥ 2 prior LOTs. In the MMRp population, ORR was similar, regardless of prior LOTs. Safety has been previously reported.¹

Conclusions Dostarlimab demonstrated antitumor activity in recurrent or advanced dMMR/MSI-H and MMRp EC regardless of number of prior LOTs. Patients with dMMR/MSI-H EC who received 1 prior LOT had slightly higher ORR than those who received ≥ 2 prior LOTs. 1. Oaknin A, et al. Ann Oncol 2020;31(suppl 4):S1142–S1215.

Plenary 2: Oral Abstract Presentations

0004/#393

DOES INTENSIVE FOLLOW-UP IMPROVE OVERALL SURVIVAL IN ENDOMETRIAL CANCER PATIENTS? RESULTS FROM THE TOTEM RANDOMIZED CONTROLLED TRIAL

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