Abstract O002/#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) *P*-value	0.36 (0.23, 0.57) <0.0001	
Median OS, months (95% CI)	NR (NR)	8.6 (5.5, 12.9)
OS HR vs TPC (95% CI) *P*-value	0.37 (0.22, 0.62) <0.0001	
ORR, % (95% CI)	40.0 (28.0, 52.9)	12.3 (5.5, 22.8)
Difference, % (95% CI) *P*-value	27.7 (12.9, 41.7) 0.0002	
Disease control rate, % (95% CI)	73.8 (61.5, 84.0)	47.7 (35.1, 60.5)
Median duration of response[a], months (range)	NR (2.1*, 20.4*)	4.1 (1.9*, 15.6*)
Median time to response[a], months (range)	2.9 (1.7, 16.3)	1.9 (1.8, 3.7)

[a]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.

O003/#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 with PD-1 ligands. GARNET is a phase 1 study assessing antitumor 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.

Abstract O003/#149 Table 1

	dMMR/MSI-H EC[a]		MMRp EC	
Variable	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)

[a]Includes 2 patients with MSI-H/MMR unknown EC; [b]Excludes hormonal therapy as single-agent treatment.

Plenary 2: Oral Abstract Presentations

O004/#393 DOES INTENSIVE FOLLOW-UP IMPROVE OVERALL SURVIVALIN ENDOMETRIAL CANCER PATIENTS? RESULTS FROM THE TOTEM RANDOMIZED CONTROLLED TRIAL

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Objectives In endometrial cancer few randomized controlled trials were conducted to assess the role of different settings of follow-up in improving overall survival. The TOTEM study (NCT00916708) was planned to compare an intensive (INT) vs minimalist (MIN) 5-year follow-up regimen in endometrial cancer patients in terms of overall survival (OS).
Methods Patients surgically treated for endometrial cancer, were stratified by center and in low (LoR) or high (HiR) risk of recurrence and then randomized to INT or MIN hospital-based follow-up regimens. The aim of the study was to demonstrate an improvement from 75% to 80% (expected hazard ratio, HR=0.78) of the 5-year OS with the INT regimen. Secondary objectives were to compare relapse free survival (RFS) and health-related quality of life (HRQL).
Results 1884 patients were randomized in 42 centers between 2008 and 2018, and 1847 patients were available for the final analysis. After a median follow-up of 66 months, the 5-year OS was 91.3%, 90.6% in the INT and 91.9% in the MIN arms, respectively (HR=1.12, 95%CI 0.85–1.48, p=0.429). Comparing the INT vs MIN arms, the 5-year OS were 94.1% and 96.8% (HR=1.48, 0.92–2.37, p=0.104) in the LoR and 85.3% and 84.7% (HR=0.96, 0.68–1.36, p=0.814) in the HiR group. The two arms did not show differences in terms of RFS and HRQL.
Conclusions Intensive follow-up in endometrial cancer treated patients did not improve OS, even in HiR patients, nor influenced health-related quality of life. Frequent routine use of imaging and laboratory exams in these patients should be discouraged.

O005/#190 WHERE THERE IS SMOKE, THERE IS FIRE: UNDERSTANDING THE IMPLICATIONS OF POSITIVE SENTINEL LYMPH NODES IN ENDOMETRIAL CANCER

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Objectives The objective of this study is to identify clinicopathologic characteristics associated with non-sentinel lymph node (SLN) metastasis and non-vaginal recurrences in patients with SLN-positive endometrial cancer (EC).
Methods Consecutive patients with surgically staged EC and at least one positive SLN were included. SLNs were ultra-staged. Positive SLNs were reviewed and patients classified according to the size of the largest SLN metastasis.
Results 103 patients (36 isolated tumor cells (ITC), 27 micrometastasis, 40 macrometastasis) were included. Multiple positive SLNs were observed in 38.8% of patients. Size of SLN metastasis (adjusted OR (aOR) 3.0 for macrometastasis vs ITC, 95%CI 1.1–8.1), and age (aOR 1.8 per 10-year increase, 95%CI 1.1–3.0) were independent predictors of multiple positive SLNs. Extracapsular compared to intracapsular invasion of the SLN metastasis was significantly associated with multiple positive SLNs at univariate analysis (71.4% vs. 33.7%, p=0.008). Forty-seven percent (18/38) of patients who underwent completion pelvic lymphadenectomy, had additional positive lymph nodes. This was associated with increased size of SLN metastasis (0/8, 5/10, and 13/20 in ITC, micro- and macrometastasis, respectively, p=0.004). SLN macrometastasis (adjusted HR (aHR) 3.4, 95%CI 1.1–11.0), non-endometrioid histology (aHR 5.7, 95%CI 1.9–17.3), and cervical stromal invasion (aHR 9.4, 95%CI 2.9–30.4) were independent predictors of non-vaginal recurrence (table 1).

Abstract O005/#190 Table 1

Characteristic	Adjusted HR (95% CI)	P
Histology		0.004
Non-endometrioid	5.09 (1.66, 15.61)	
Endometrioid	Reference	
Cervical stromal invasion		0.002
No	Reference	
Yes	6.89 (2.04, 23.23)	
Size of SLN metastasis		0.04
ITC/micrometastasis	Reference	
Macrometastasis	3.41 (1.05, 11.09)	

Conclusions Size and location of SLN metastasis can predict an increased risk of multiple positive SLNs, non-SLN positive nodes, and non-vaginal recurrence in SLN positive EC patients. These factors should be assessed when considering adjuvant treatment in these high-risk patients.

O006/#340 MINIMALLY INVASIVE SURGERY IN ADVANCED ENDOMETRIAL CARCINOMA IS ASSOCIATED WITH AN INCREASED RISK FOR LOCAL RECURRENCE

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Objectives To compare oncological outcomes of women with stage II -IIIc endometrial cancer (EC) who underwent minimally invasive surgery (MIS) versus laparotomy.
Methods A retrospective cohort study in an academic multicenter setting. Consecutive women with EC treated at 11 Israeli institutions between 2002 and 2017 were recorded in an assimilated database with a median follow-up of 52 months (range 12–120 months). Women with stage II -IIIc were stratified into groups by intentional route of surgery; MIS vs. laparotomy. Clinical, pathological and outcome data were compared.

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