Supplementary Table S 7. ESMO-MCBS table for new therapies/indications in endometrial cancer

Therapy	Disease setting	Trial	Control	Absolute survival gain	HR (95% CI)	QoL/toxicity	ESMO-MCBS score[a]
Dostarlimab	Treatment of adult patients with dMMR/MSI-H recurrent or advanced endometrial cancer that have progressed on or following prior treatment with a platinum-containing regimen	GARNET[1-3] Phase I NCT02715284	Single arm	ORR: 43.5% Median DoR: >9 months (NR) Median PFS: 12.2 months			3 (Form 3)
Pembrolizumab[b]	Patients with unresectable or metastatic TMB-H solid tumours that have progressed following prior treatment and have no alternative treatment options	KEYNOTE-158[4] Phase II NCT02628067	Single arm cohort study	ORR: 29% Median DoR: >9 months (NR) Median PFS: 2.1 months			3 (Form 3)
Pembrolizumab	Patients with unresectable or metastatic dMMR/MSI-H solid tumours that have	KEYNOTE- 158[5, 6] Phase II	Single arm cohort study	ORR: 57.1% Median PFS: 25.7 months		QoL was not a pre-specified endpoint	3 (Form 3)

	progressed following prior treatment and have no alternative treatment options	NCT02628067		Median DoR: >9 months (NR)			
Pembrolizumab	Patients with advanced or recurrent dMMR/MSI-H endometrial cancer who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or RT	KEYNOTE- 158[7, 8] Phase II NCT02628067	Single arm cohort study	ORR: 48% Median PFS: 13.1 months Median DoR: >9 months (NR)		QoL was not a pre-specified endpoint	3 (Form 3). Score .
Pembrolizumab + lenvatinib[c]	Patients with advanced or recurrent endometrial cancer who have progressed following prior platinum-containing therapy in any setting and who are not candidates for curative surgery or RT	KEYNOTE-775[9] Phase III NCT03517449	TPC (paclitaxel or doxorubicin) Median OS: 11.4 months Median PFS: 3.8 months	OS gain: 6.9 months PFS gain: 3.4 months	OS HR: 0.62 (0.51-0.75) PFS HR: 0.56 (0.47-0.66)	No difference in QoL between treatment groups	4 (Form 2a)
Pembrolizumab + lenvatinib[d]	Patients with advanced endometrial cancer that is not MSI-H or	KEYNOTE- 775[9] Phase III	TPC (paclitaxel or doxorubicin)			No difference in QoL between treatment groups	4 (Form 2a)

	dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or RT	NCT03517449	Median OS: 12.0 months Median PFS: 3.8 months	OS gain: 5.4 months PFS gain: 2.8 months	OS HR: 0.68 (0.56-0.84) PFS HR: 0.6 (0.50-0.72)		

CI, confidence interval; dMMR, mismatch repair deficient; DoR, duration of response; EMA, European Medicines Agency; ESMO- MCBS, ESMO-Magnitude of Clinical Benefit Scale; FDA, Food and Drug Administration; HR, hazard ratio; MSI-H, microsatellite instability-high; NR, not reached; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient; QoL, quality of life; RT, radiotherapy; TMB-H, tumour mutational burden-high; TPC, treatment of physician's choice.

[a] The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee. ESMO-MCBS v1.1.[10] was used to calculate scores for new therapies/indications approved by the EMA or FDA. (https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms).

[b] FDA approved; not EMA approved.

[c] EMA approval is irrespective of MSI/MMR status and so data shown are for the entire study population.

[d] FDA approval is restricted to patients whose tumours are not MSI-H or dMMR and so data shown are for the pMMR study population.

References:

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