cancer patients versus non-cancer controls across all phases of care (except terminal phase costs for cervical cancer). Outpatient costs were the major driver of costs across all post-diagnosis phases (figure 1 and 2).

Conclusion The mean phase-specific costs followed the following order: Terminal > Initial > Continuation > Pre-diagnosis. This study highlights the substantial cost burden associated with cervical/endometrial cancer, and cost variation by phases of care.

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SAFETY AND ANTITUMOR ACTIVITY OF DOSTARLIMAB IN PATIENTS (PTS) WITH ADVANCED OR RECURRENT DNA MISMATCH REPAIR DEFICIENT (dMMR) OR PROFICIENT (MMRp) ENDOMETRIAL CANCER (EC): RESULTS FROM THE GARNET STUDY

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Introduction/Background Dostarlimab is a humanised programmed death (PD)-1 receptor monoclonal antibody that

Abstract 385 Table 1 Antitumour activity

Variable	dMMR EC, n=103	MMRp EC, n=142
Median follow-up time, mo	16.3	11.5
Objective response rate*, n (%), 95% CI)	46 (44.7%, 34.9–54.8)	19 (13.4%, 8.3–20.1)
Complete response, n (%)	11 (10.7)	3 (2.1)
Partial response, n (%)	35 (34.0)	16 (11.3)
Stable disease, n (%)	13 (12.6)	31 (21.8)
Progressive disease, n (%)	39 (37.9)	77 (54.2)
Not evaluable, n (%)	3 (2.9)	0
Not done, n (%)	2 (1.9)	15 (10.6)
Disease control rate†, n (%), 95% CI)	59 (57.3%, 47.2–67.0)	50 (35.2%, 27.4–43.7)
Response ongoing, n (%)	41 (89.1)	12 (63.2)
Median duration of response, (range) mo	Not reached (2.63–28.09+)	Not reached (1.54+–30.36+)
Kaplan–Meier estimated probability of remaining in response		
at 6 mo, %	97.8	83.0
at 12 mo, %	90.6	61.3
at 18 mo, %	79.2	61.3

*Responses required confirmation at a subsequent scan; SD had to be observed at ≥12 weeks on study to qualify as SD; †Includes confirmed CR, PR or SD at ≥12 weeks.
CR, complete response; dMMR, mismatch mutation repair deficient; EC, endometrial cancer; MMRp, mismatch mutation repair proficient, ORR, objective response rate; PR, partial response; SD, stable disease.

Abstract 385 Table 2 Most common adverse events

MedDRA preferred term, n (%)	dMMR EC N=126	MMRp EC N=145	Overall N=271
Any grade TRAEs			
Fatigue	17 (13.5)	30 (20.7)	47 (17.3)
Diarrhoea	20 (15.9)	19 (13.1)	39 (14.4)
Nausea	16 (12.7)	21 (14.5)	37 (13.7)
Grade ≥3 TRAEs			
Anaemia	5 (4.0)	2 (1.4)	7 (2.6)
Alanine aminotransferase increased	2 (1.6)	2 (1.4)	4 (1.5)
Diarrhoea	2 (1.6)	2 (1.4)	4 (1.5)
TRAEs leading to discontinuation			
Alanine aminotransferase increased	1 (0.8)	2 (1.4)	3 (1.1)
Aspartate aminotransferase increased	1 (0.8)	1 (0.7)	2 (0.7)
Transaminases increased	2 (1.6)	0	2 (0.7)

dMMR, mismatch mutation repair deficient; EC, endometrial cancer; MMRp, mismatch mutation repair proficient; TRAE, treatment-related adverse event.

blocks interaction with the PD-1 ligands, PD-L1 and -L2. GARNET is a phase 1 study assessing antitumour activity and safety of dostarlimab monotherapy in patients with advanced solid tumours.

Methodology This multicentre, open-label, single-arm study is being conducted in 2 parts, dose escalation and expansion. Here we report on 2 independent expansion cohorts of patients with recurrent or advanced endometrial cancer (EC) that progressed on or after a platinum-based chemotherapy regimen. Assignment to cohort A1 (mismatch mutation repair deficient [dMMR] EC) or cohort A2 (mismatch mutation repair proficient [MMRp] EC) was determined by immunohistochemistry (IHC) testing. Patients received 500 mg dostarlimab intravenously once every 3 weeks for 4 cycles, then 1000 mg once every 6 weeks until disease progression, discontinuation or withdrawal. The primary endpoints are objective response rate (ORR) and duration of response (DOR) by blinded independent central review using RECIST version 1.1.

Results In total, 126 dMMR and 145 MMRp pts identified by IHC were enrolled and dosed. Of these, 103 dMMR and 142 MMRp pts had measurable disease as baseline and sufficient follow-up time (6 months) for efficacy analyses, respectively. Patients that progressed prior to 6 months were included in the evaluable population. ORR for dMMR EC was 44.7%; ORR for MMRp EC was 13.4% (table 1). Median DOR and OS were not reached in either cohort. Overall, 15 pts (5.5%) discontinued treatment due a TRAE (5 dMMR, 10 MMRp). Safety by cohort and overall are shown in table 2. There were no deaths attributed to dostarlimab.

Conclusion Dostarlimab demonstrated durable antitumour activity in both dMMR and MMRp advanced/recurrent EC. dMMR status by IHC was associated with a higher response rate. Dostarlimab demonstrated a notable disease control rate (35.2%; 2.1% complete response, 11.3% partial response, 21.8% stable disease) in patients with MMRp EC, which comprised a higher percentage of patients with Type II EC and is historically associated with a worse prognosis. No new safety signals were detected. These cohorts are the largest prospective evaluation of a PD-(L)1 therapy in EC to date.

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PATIENT-REPORTED OUTCOMES (PROS) IN THE GARNET TRIAL IN PATIENTS (PTS) WITH ADVANCED OR RECURRENT MISMATCH REPAIR DEFICIENT/ MICROSATTELITE INSTABILITY-HIGH (dMMR/MSI-H) ENDOMETRIAL CANCER (EC) TREATED WITH DOSTARLIMAB

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Introduction/Background PROs enable direct measurement of the experiences of pts with cancer related to an intervention. Regulators increasingly use PROs to inform the risks and benefits of new drug candidates, focusing on 3 core concepts: physical functioning (PF), disease-related symptoms (DRS), and symptomatic adverse events (AEs).

Dostarlimab is an investigational anti-programmed death-1 monoclonal antibody that has shown activity in pts with advanced dMMR EC (objective response rate, 42%; disease control rate, 58%) and an acceptable safety profile. Here, we report on PROs in pts treated with dostarlimab in the single-arm GARNET trial.

Methodology Pts with recurrent or advanced dMMR/MSI-H EC that progressed on a platinum regimen received 500 mg Q3W*4 of dostarlimab, then 1000 mg Q6W until disease progression or discontinuation (DC). PRO assessment, an exploratory endpoint, was measured using the EORTC-QLQ-C30. PROs were collected at baseline (BL), each dose cycle, and after DC. For PF and DRS (pain and fatigue), we conducted multi-item descriptive analyses, including change from BL. For symptomatic AEs and tolerability (nausea, vomiting, constipation, diarrhoea, tiredness/fatigue), we conducted item-level analyses to understand response distribution and change in response categories from BL: improved, stable, and 1-, 2-, or 3-category worsening.

Results PRO data were available for 66/104 pts who received ≥1 dose of dostarlimab. Questionnaire compliance was consistent across domains, ranging from 100% at BL to 45% at cycle 7. Pain, fatigue, and PF were maintained above BL starting at cycles 1, 3, and 4, respectively. Symptomatic AEs were experienced by a minority of pts, with <25% and <6% of pts having 1- or ≥2-category worsening, respectively. Improved scores were reported by 6% to 37% of pts.

Conclusions PROs from the GARNET trial showed that dostarlimab was generally well tolerated and disease-related symptoms were improved or maintained while on treatment. These data, along with the efficacy and safety profile of dostarlimab, support use of dostarlimab in pts with dMMR/MSI-H advanced EC.

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