2022-RA-1009-ESGO IMMUNE-RELATED ENDPOINTS IN PATIENTS WITH ADVANCED OR RECURRENT ENDOMETRIAL CANCER TREATED WITH DOSTARLIMAB IN THE GARNET STUDY

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Introduction/Background Dostarlimab is a programmed death 1 (PD-1) inhibitor approved in the US as monotherapy in patients with mismatch repair deficient (dMMR) advanced/recurrent endometrial cancer (EC) that has progressed on or after platinum-based chemotherapy or dMMR solid tumours that have progressed on or after prior treatment, with no satisfactory alternative treatment options; and in the EU as monotherapy in patients with dMMR/microsatellite instability-high (MSI-H) advanced/recurrent EC that has progressed on or after platinum-based chemotherapy. We report efficacy endpoints by immune-related RECIST (irRECIST) per investigator assessment (IA) for the EC cohorts of the GARNET trial.

Methodology GARNET is a multicentre, open-label, single-arm phase 1 study. Assignment to cohort A1 (dMMR/MSI-H EC) or A2 (mismatch repair proficient [MMRp]/microsatellite stable [MSS] EC) was based on local assessment. Patients received 500 mg of dostarlimab intravenously Q3W for 4 cycles, then 1000 mg Q6W until disease progression, discontinuation, or withdrawal. Immune-related endpoints (irORR, irDOR, and irPFS) were prespecified secondary endpoints.

Results The irRECIST efficacy-evaluable population included 152 patients with dMMR/MSI-H EC and 160 patients with MMRp/MSS EC with measurable disease at baseline and ≥6 months' follow-up per IA. irORR and irDOR were similar to the primary endpoints of ORR and DOR by BICR per RECIST v1.1 (table 1). For dMMR/MSI-H, median irPFS was 11.2 mo versus median PFS of 6.0 mo, although the probability of remaining progression free at 6, 12, or 18 mo was similar. Safety was previously reported.

Abstract 2022-RA-1009-ESGO Table 1

Immune-related secondary endpoints (irRECIST by IA)			Primary endpoints (RECIST v1.1 by BICR)		
Variable	dMMR/MSI-H EC N=152[a]	MMRp/MSS EC N=160[a]	Variable	dMMR/MSI-H EC N=143	MMRp/MSS EC N=156
Median follow-up, mo	27.7	33.1	Follow-up, median, mo	27.6	33.0
irORR, n (%, 95% CI) irCR, n (%) irPR, n (%)	73 (48.0, 39.9–56.3) 20 (13.2) 53 (34.9)	24 (15.0, 9.9–21.5) 4 (2.5) 20 (12.5)	ORR, n (%, 95% CI) CR, n (%) PR, n (%)	65 (45.5, (37.1–54.0) 23 (16.1) 42 (29.4)	24 (15.4, 10.1–22.0) 4 (2.6) 10 (12.8)
irDCR, n (%, 95% CI)[b]	99 (65.1, 57.0–72.7)	65 (40.6, 32.9–48.7)	DCR, n (%, 95% CI)[c]	86 (60.1, 51.6–68.2)	53 (34.0, 26.6–42.0)
Response ongoing, n (%)	54 (74.0)	7 (29.2)	Response ongoing, n (%)	54 (83.1)	9 (37.5)
Median irDOR (95% CI), mo	NR (34.7–NR)	14.0 (7.0–38.1)	Median DOR (95% CI), mo	NR (38.9–NR)	19.4 (8.2–NR)
Median irPFS, % (95% CI), mo	11.2 (5.6–18.0)	2.8 (2.6–3.9)	Median PFS, % (95% CI), mo	6.0 (4.1–18.0)	2.7 (2.6–2.8)
Estimated probability of irPFS, % (95% CI) 6 mo 9 mo 12 mo	 56.5 (48.0–64.0) 52.5 (43.8–60.0) 48.6 (40.3–56.5)	 28.9 (21.8–36.3) 20.4 (14.3–27.3) 14.8 (9.6–21.1)	Estimated probability of PFS, % (95% CI) 6 mo 9 mo 12 mo	 49.5 (41.0–57.5) 48.0 (39.4–56.0) 46.4 (37.8–54.5)	 22.9 (16.5–30.0) 15.5 (10.1–22.0) 13.3 (8.3–19.5)

[a]irRECIST includes 9 patients with dMMR/MSI-H EC and 4 patients with MMRp/MSS EC who were assessed as having measurable disease at baseline per IA.
[b]Includes irCR, irPR, and irSD ≥12 weeks.
[c]Includes CR, PR, and SD ≥12 weeks.
BICR, blinded independent central review; CR, complete response; DCR, disease control rate; dMMR, mismatch repair deficient; DOR, duration of response; EC, endometrial cancer; IA, investigator assessment; ir, immune-related; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable; NR, not reached; ORR, objective response rate; PFS, progression-free survival; PR, partial response; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease.

Conclusion In line with the study primary endpoints, secondary efficacy endpoints by irRECIST demonstrate the benefit of dostarlimab in patients with EC.

2022-RA-1012-ESGO THE ROLE OF INFLAMMATORY MARKERS IN THE PREOPERATIVE DIAGNOSIS OF ENDOMETRIAL CANCER AND ENDOMETRIAL HYPERPLASIA

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Introduction/Background Inflammation and immunogenesis are important for cancer progression and metastasis. Blood neuthrophile lymphocyte ratio (NLR) and platelets lymphocytes ratio(PLR) are basic indicators of systemic inflamatory response, In addition high NLR is detected in patients with endometrial cancer . The aim of this study is to investigate the predictive role of NLR and PLR in cases of endometrial hyperplasia and cancer.

Methodology This retrospective study was performed between 2015–2020 with 469 cases, 78 nonatypical endometrial hyperplasia, 28 atypical endometrial hiperplasia, 79 endometrial adenocarcinoma and 284 controls who underwent an endometrial biopsy due to abnormal uterine bleeding and had a normal histopathology in two tertiary clinics. Blood samples were drawn from all patients before endometrial biopsy . Blood cell counts, NLRs and PLRs were compared among these groups.

Results The mean age of 469 patients was 49,01 ±49,01. The mean age was 47,49± 6,85 in group 1, 50,93 ± 10,56 in group 2, 60,95 ±8,81 in group 3 and 45,92± 6,80 in control group. The difference of age was significant between group 3 and the other groups ($p<0.001$). Based on lymphocyte, platelet counts and PLRs, there was no significant difference among the groups ($P>0.05$). The median neuthrophile counts in groups 1,2,3 and control were 3,89, 5,40, 5,30 and 3,90 respectively and there was a statistically significant difference between neuthrophile counts of the groups ($p<0.001$) The median NLRs in groups 1, 2, 3 and control were 1,81, 2,27, 2,60 and 1.91, respectively, There was a statistically significant