2022 ASCO® ANNUAL MEETING

Dostarlimab in Advanced/Recurrent Mismatch Repair Deficient/Microsatellite Instability–High or Proficient/Stable Endometrial Cancer: the GARNET study

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Author Conflicts of Interest

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- **Dr. Tinker** reports institutional grants from AstraZeneca; and personal fees from AstraZeneca and Eisai.
- **Ms. Zildjian and Drs. Duan, Zografos,** and **Veneris** are employees of GlaxoSmithKline.

Background

- Endometrial cancer is the most common gynecological malignancy in the US and EU[1,2]
- The incidence of endometrial cancer is rising globally[1–3]
- Overall survival is typically <1 year for patients with disease progression that occurs on or after first-line therapy
- There is no standard second-line therapy, and new therapeutics options are needed

1. Siegel RL, et al. *CA Cancer J Clin*. 2022;72:7–33. 2. Lortet-Tieulent J, et al. *J Natl Cancer Inst*. 2018;110(4):354–361. 3. Guo F, et al. *J Clin Oncol.* 2021;39(suppl 15):abstr 5578.

Dostarlimab

- Dostarlimab is an anti–PD-1 monoclonal antibody that blocks interaction with the ligands PD-L1 and PD-L2
  - In the US, dostarlimab is approved as a monotherapy in adult patients with the following:

    - dMMR recurrent or advanced endometrial cancer that has progressed on or after a platinum-containing regimen[1]
    - dMMR solid tumors that have progressed on or after prior treatment, with no satisfactory alternative treatment options[1]
      - The US indications are approved under accelerated approval based on tumor response rate and durability of response[1]

In the EU, dostarlimab is approved as a monotherapy in patients with dMMR/MSI-H recurrent or advanced endometrial cancer that has progressed on or after treatment with a platinum-containing regimen[2]

dMMR, mismatch repair deficient; MSI-H, microsatellite instability–high; PD-1, programmed death 1; PD-L1, programmed death ligand 1; PD-L2, programmed death ligand 2.

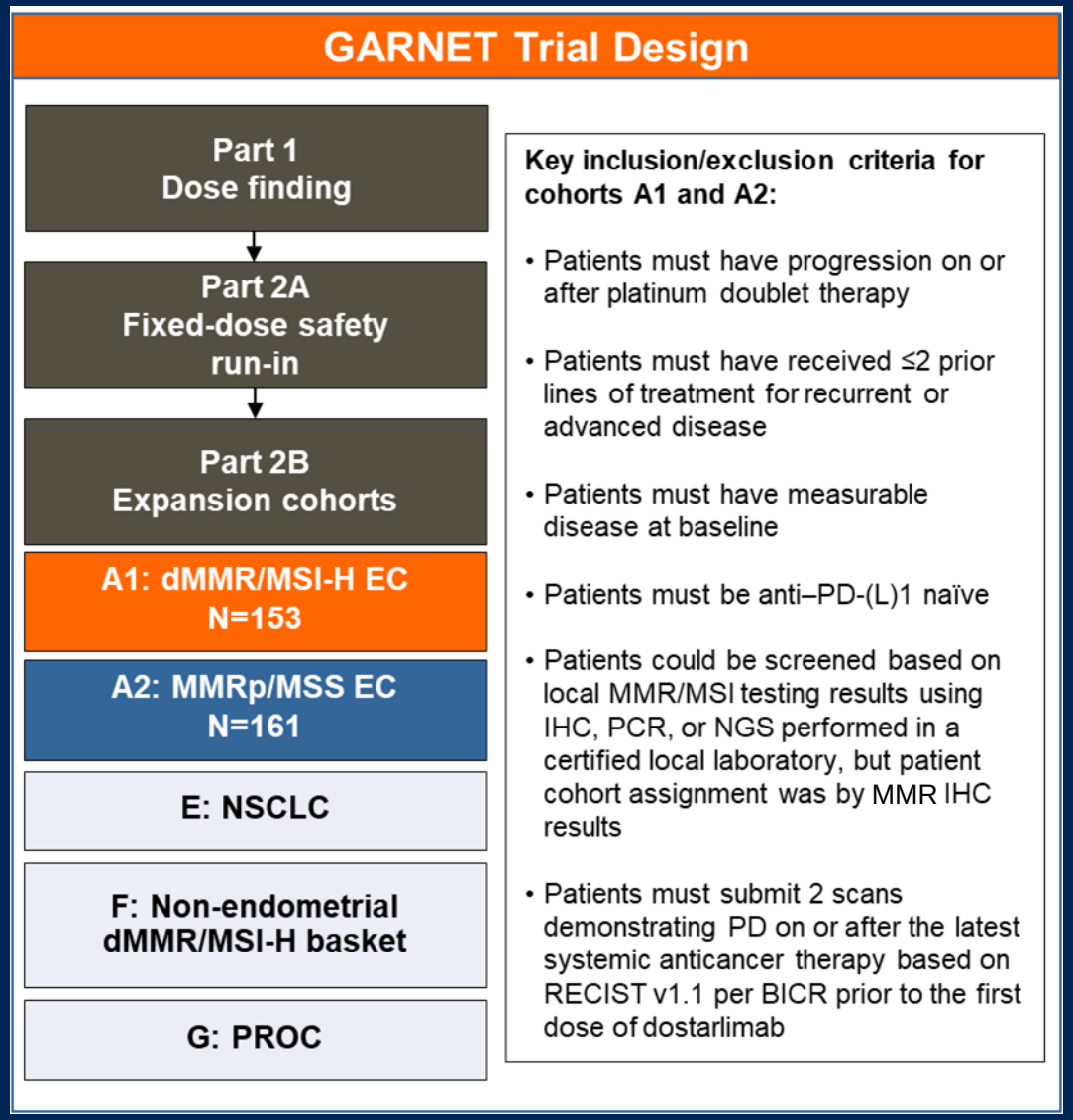
1. GlaxoSmithKline. Jemperli. Accessed January 12, 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761223s000lbl.pdf. 2. European Medicines Agency. Jemperli. Accessed February 1, 2022. https://www.ema.europa.eu/en/medicines/human/EPAR/jemperli.

Objective

- We report efficacy and safety of dostarlimab monotherapy in the 2 expansion cohorts of the GARNET trial that enrolled patients with advanced/recurrent endometrial cancer
- Data are from the third prespecified interim analysis and provide long-term follow-up on enrolled patients
(Data cutoff date: November 1, 2021)

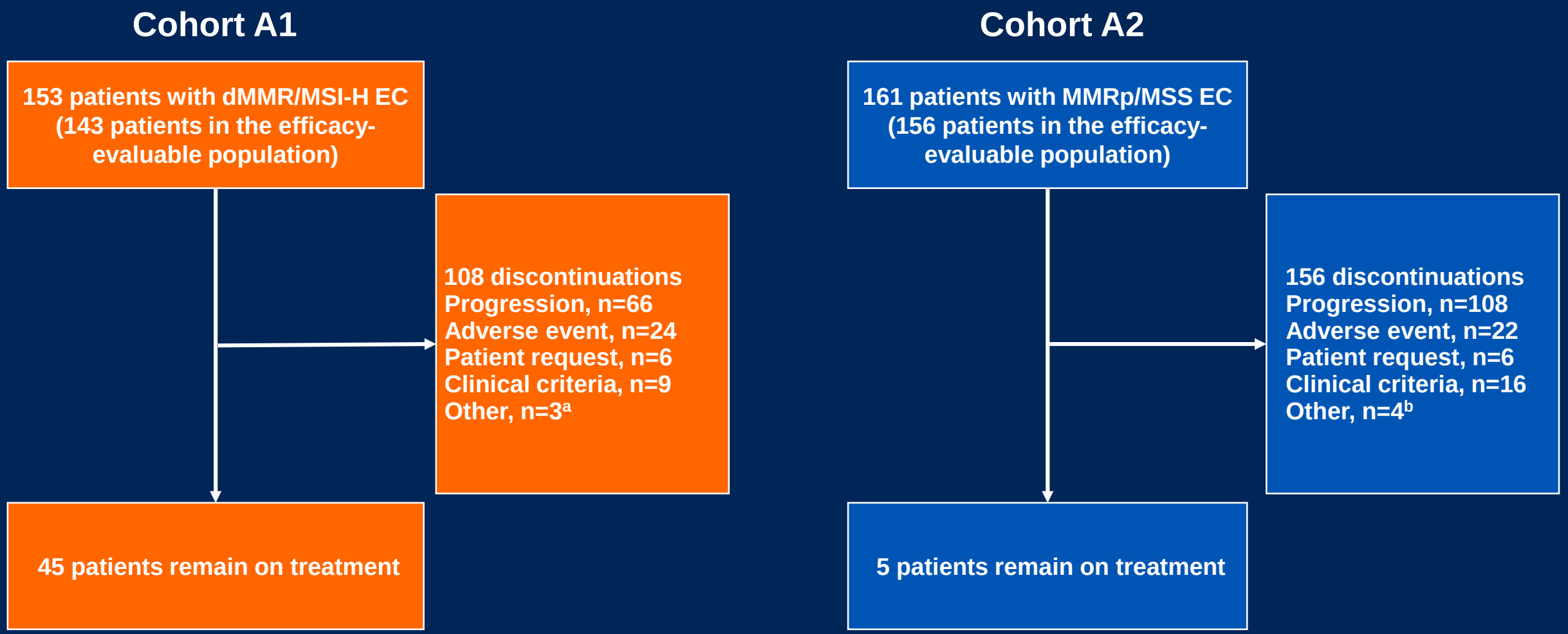
Methods

- GARNET is a phase 1, multicenter, open-label, single-arm study of dostarlimab monotherapy in patients with advanced or recurrent solid tumors
- Patients were enrolled to cohort A1 (dMMR/MSI-H) or cohort A2 (MMRp/MSS) based on MMR IHC assessment
- Patients received 500 mg IV dostarlimab every 3 weeks for 4 cycles, followed by 1000 mg IV every 6 weeks until disease progression, discontinuation, or withdrawal
- Primary endpoints were evaluation of antitumor activity (in terms of ORR and DOR by BICR per RECIST v1.1), safety, and tolerability



BICR, blinded independent central review; dMMR, mismatch repair deficient; DOR, duration of response; EC, endometrial cancer; IHC, immunohistochemistry; IV, intravenous; MMR, mismatch repair; MMRp, mismatch repair proficient; MSI, microsatellite instability; MSI-H, microsatellite instability–high; MSS, microsatellite stable; NGS, next-generation sequencing; NSCLC, non–small cell lung cancer; ORR, objective response rate; PCR, polymerase chain reaction; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PROC, platinum-resistant ovarian cancer; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

Enrollment and Outcomes



10 (cohort A1) and 5 (cohort A2) patients were excluded from the efficacy-evaluable population because they had no measurable disease at baseline per BICR.
[a]3 patients in cohort A1 died of disease progression. [b]2 patients in cohort A2 died of disease progression, 1 patient was sent to hospice care, 1 patient discontinued because of a joint decision between patient and investigator.
BICR, blinded independent central review; dMMR, mismatch repair deficient; EC, endometrial cancer; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable.

Demographics and Baseline Characteristics

Characteristic, n (%)	dMMR/MSI-H EC N=143	MMRp/MSS EC N=156
Age, median (range), years	65.0 (39–85)	66.0 (30–86)
FIGO disease stage at diagnosis[a]		
Stage I or II	62 (43.4)	57 (36.5)
Stage III or IV	81 (56.6)	98 (62.8)
Histology		
Grade 1 or 2 endometrioid carcinoma	92 (64.3)	36 (23.1)
Serous	7 (4.9)	63 (40.4)
Grade 3 endometrioid	21 (14.7)	14 (9.0)
Clear cell	1 (0.7)	11 (7.1)
Squamous	1 (0.7)	3 (1.9)
Undifferentiated	4 (2.8)	3 (1.9)
Carcinosarcoma	0	2 (1.3)
Mixed carcinoma	7 (4.9)	11 (7.1)
Unspecified	4 (2.8)	9 (5.8)
Other[b]	4 (2.8)	4 (2.6)
Unknown	2 (1.4)	0

Characteristic, n (%)	dMMR/MSI-H EC N=143	MMRp/MSS EC N=156
Prior anticancer treatment	143 (100)	156 (100)
Prior lines of therapy, n (%)[c]		
1	90 (62.9)	72 (46.2)
2	35 (24.5)	67 (42.9)
≥3	18 (12.6)	17 (10.9)
Patients with only adjuvant or neoadjuvant therapy	49 (34.3)	42 (26.9)
Neoadjuvant setting only	3 (2.1)	3 (1.9)
Adjuvant setting only	44 (30.8)	39 (25.0)
Only adjuvant and neoadjuvant	2 (1.4)	0
Prior radiation, n (%)	101 (70.6)	95 (60.9)

[a]One patient with MMRp EC had disease status/stage unknown. [b]Other includes adenosquamous, dedifferentiated, endometrial adenocarcinoma, endometrial adenocarcinoma not otherwise specified, endometrial neuroendocrine carcinoma, high-grade uterine carcinoma, and undifferentiated clear cell carcinoma. [c]Includes lines of therapy in the adjuvant setting.
dMMR, mismatch repair deficient; EC, endometrial cancer; FIGO, International Federation of Gynecology and Obstetrics; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable.

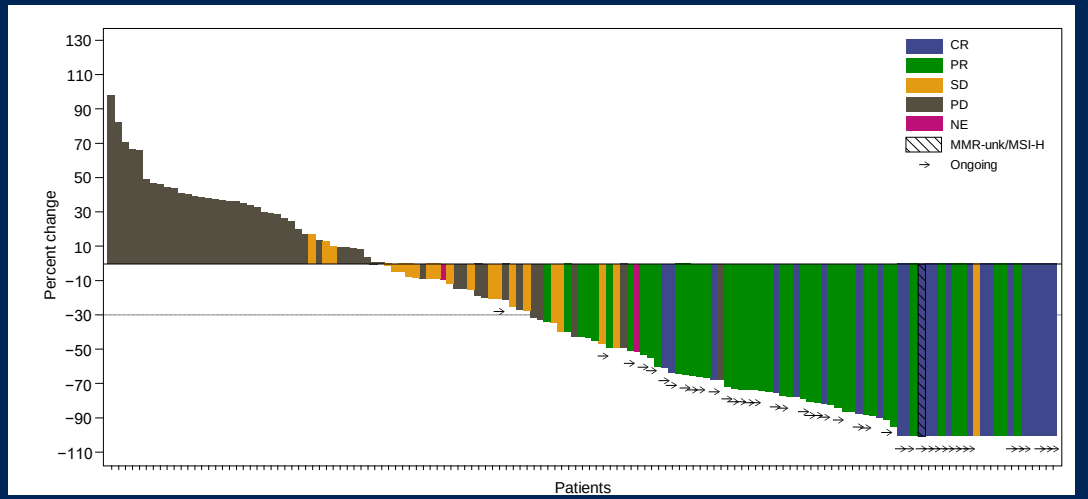
Primary Endpoint Analysis

	dMMR/MSI-H EC N=143	MMRp/MSS EC N=156
Median follow-up time, months	27.6	33.0
ORR, % (95% CI; n/N)	**45.5%** (37.1–54.0; 65/143)	**15.4%** (10.1–22.0; 24/156)
Complete response, n (%)	23 (16.1)	4 (2.6)
Partial response, n (%)	42 (29.4)	20 (12.8)
Stable disease, n (%)	21 (14.7)	29 (18.6)
Progressive disease, n (%)	51 (35.7)	88 (56.4)
Not evaluable, n (%)	6 (4.2)	15 (9.6)
Median time from cycle 1 day 1 to best overall response, mo		
Complete response	2.79	2.81
Partial response	2.69	2.79
Disease control rate, % (95% CI; n/N)	60.1% (51.6–68.2; 86/143)	34.0% (26.6–42.0; 53/156)
Response ongoing, n (%)	54 (83.1)	9 (37.5)
Median duration of response (range), months	**NR** (1.18+ to 47.21+)	**19.4** (2.8 to 47.18+)
Probability of maintaining response, %		
6 months	96.8	82.6
12 months	93.3	60.3
24 months	83.7	44.2

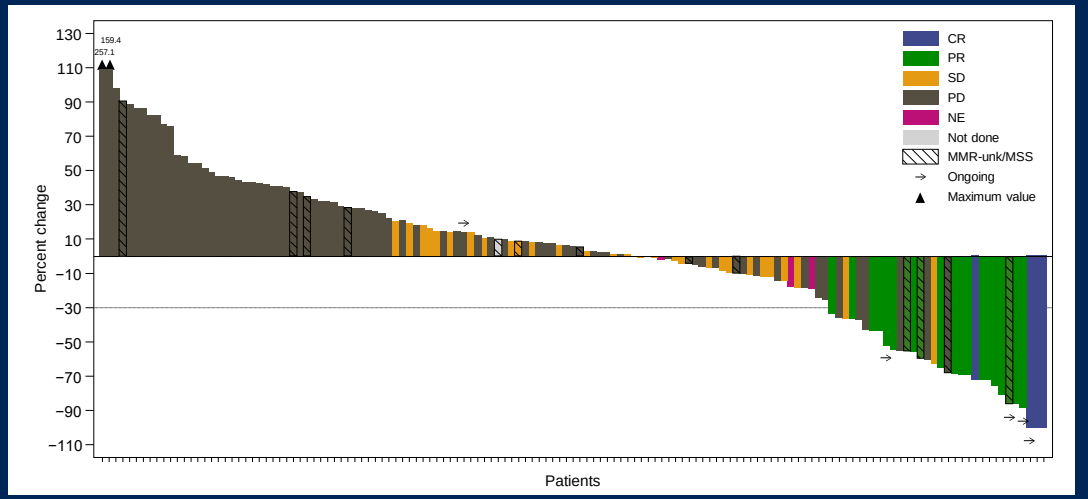
dMMR, mismatch repair deficient; EC, endometrial cancer; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable; NR, not reached; ORR, objective response rate.

Best Volume Change in Target Lesions Based on BICR per RECIST v1.1

dMMR/MSI-H EC

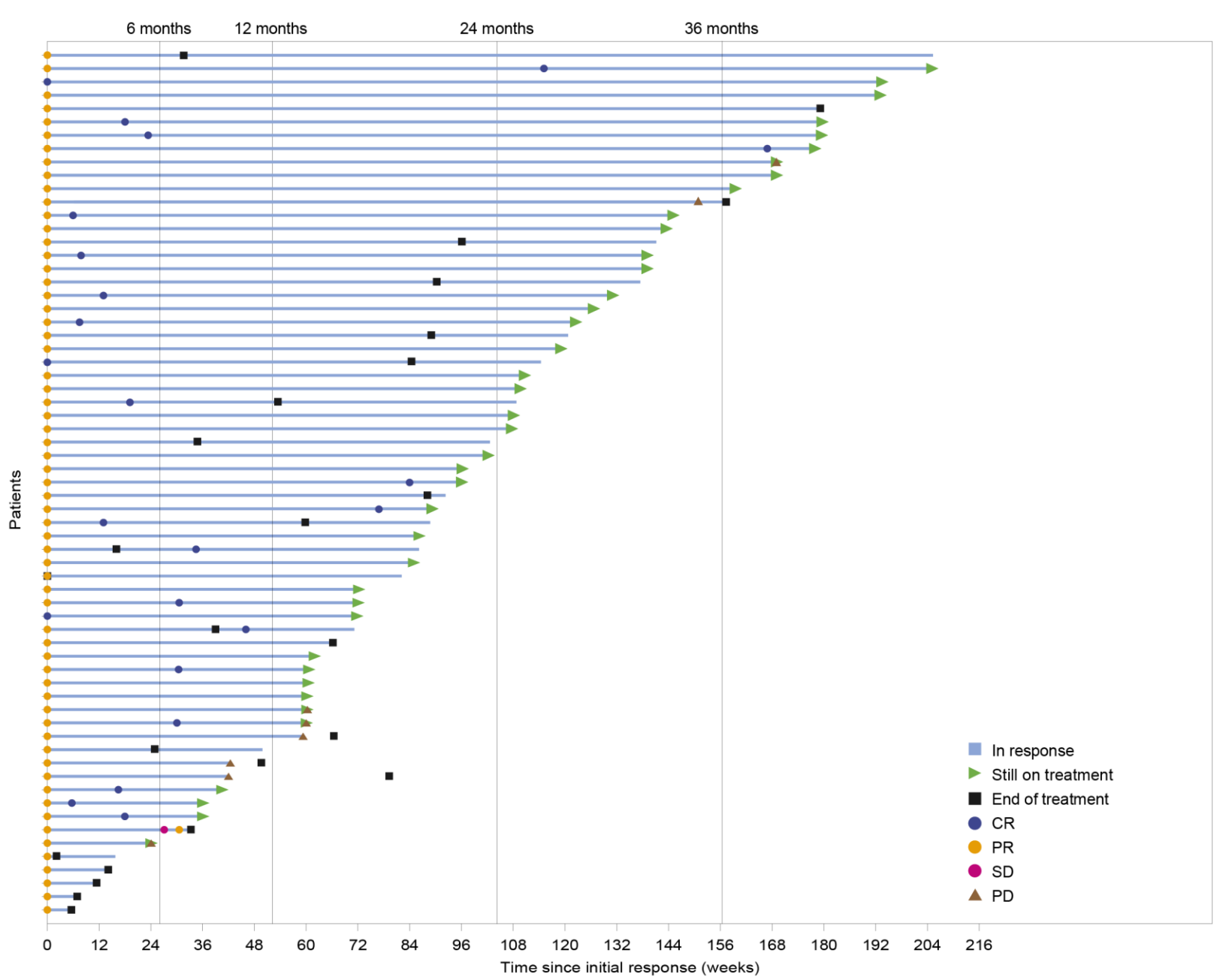


MMRp/MSS EC



BICR, blinded independent central review; CR, complete response; dMMR, mismatch repair deficient; EC, endometrial cancer; MMRp, mismatch repair proficient; MMR-unk, mismatch repair unknown; MSI-H, microsatellite instability–high; MSS, microsatellite stable; NE, not evaluated; PD, progressive disease; PR, partial response; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease.

Duration of Response in Responders: dMMR/MSI-H



- Responses were durable, as shown with increased median duration of follow-up of 27.6 months
- Median duration of response was not reached
- Probability of remaining in response at 24 months was 83.7%

CR, complete response; dMMR, mismatch repair deficient; MSI-H, microsatellite instability–high; PD, progressive disease; PR, partial response; SD, stable disease.

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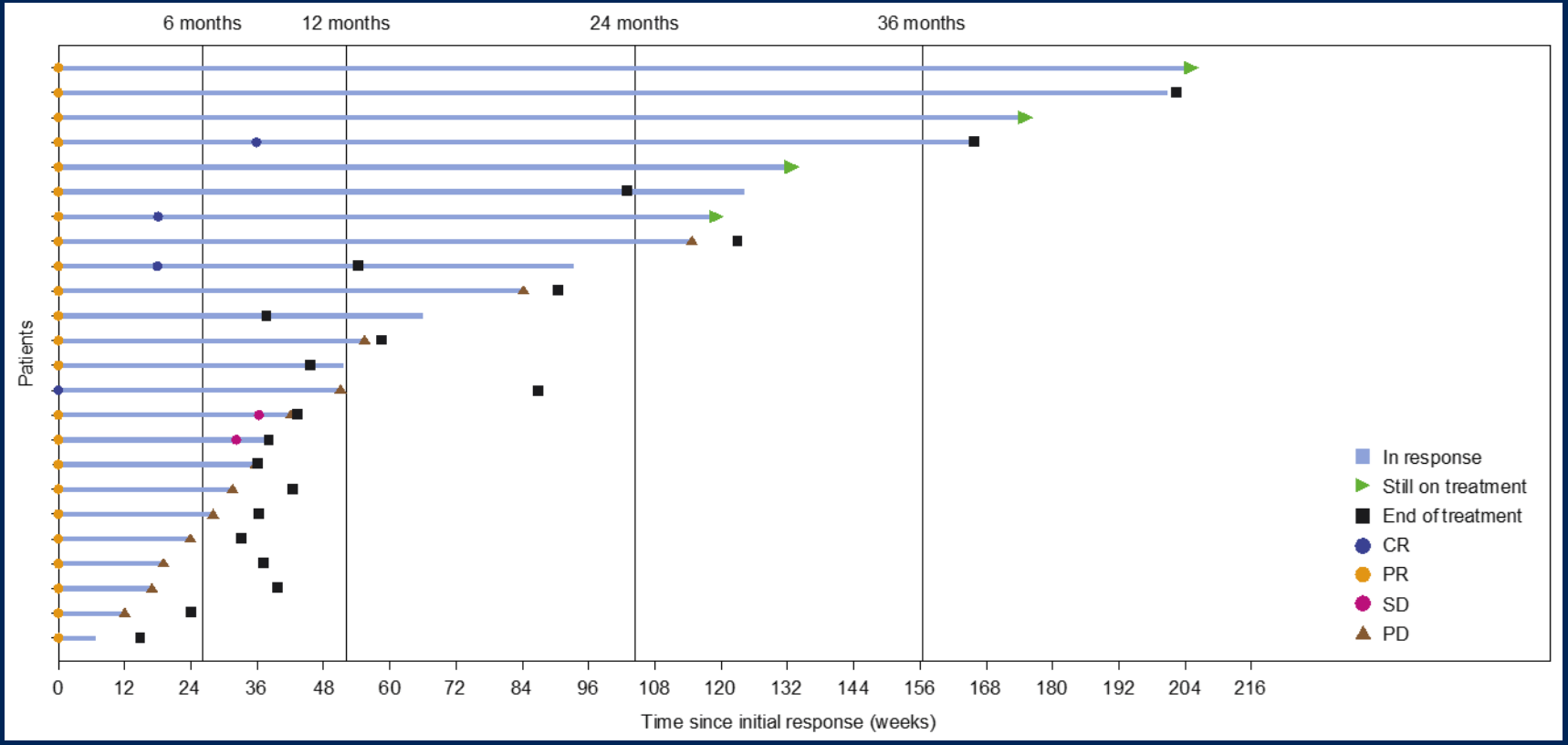
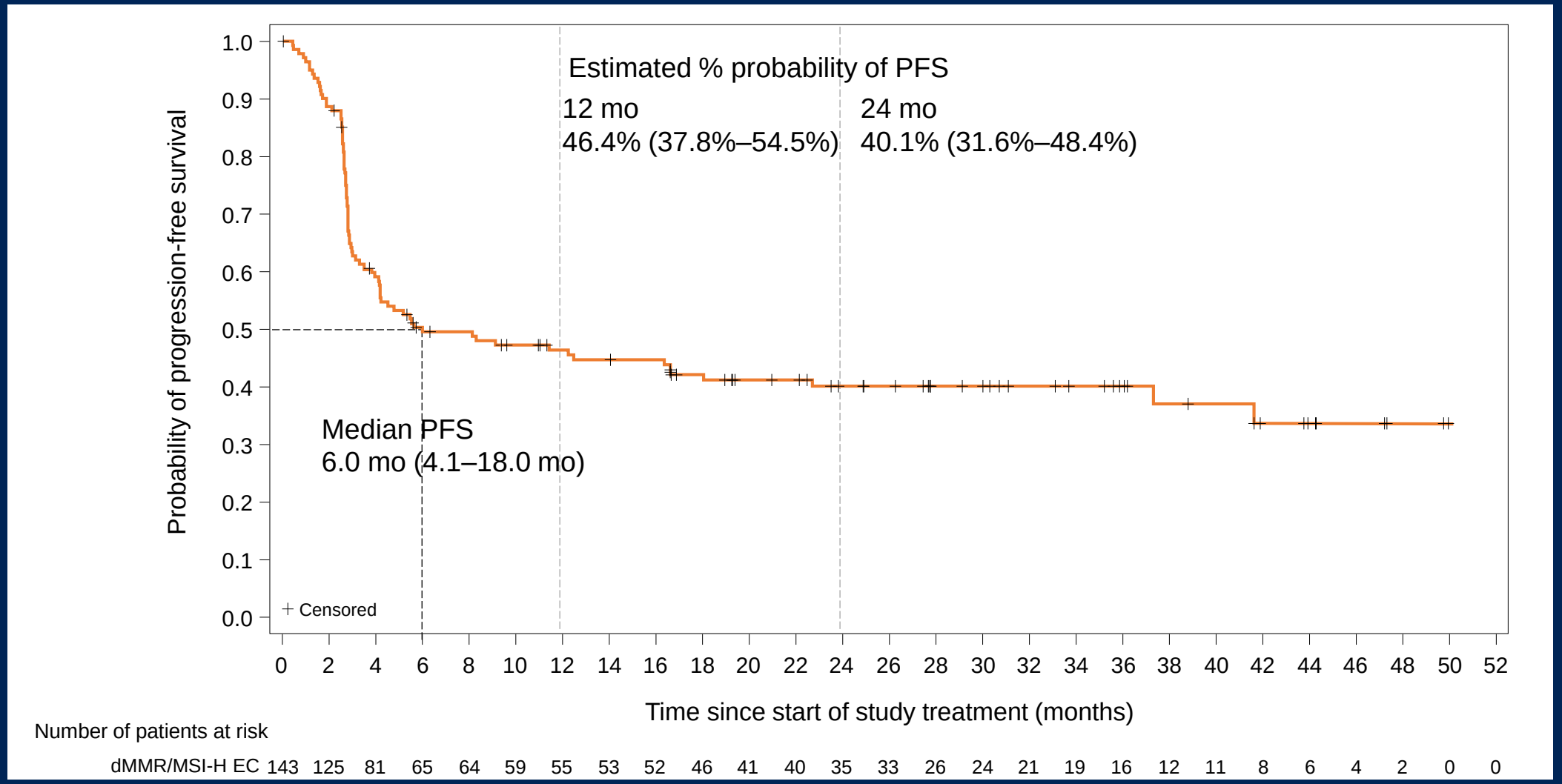
Duration of Response in Responders: MMRp/MSS



- Responses were durable, as shown with increased median duration of follow-up of 33.0 months
- Median duration of response was 19.4 months
- Probability of remaining in response at 24 months was 44.2%

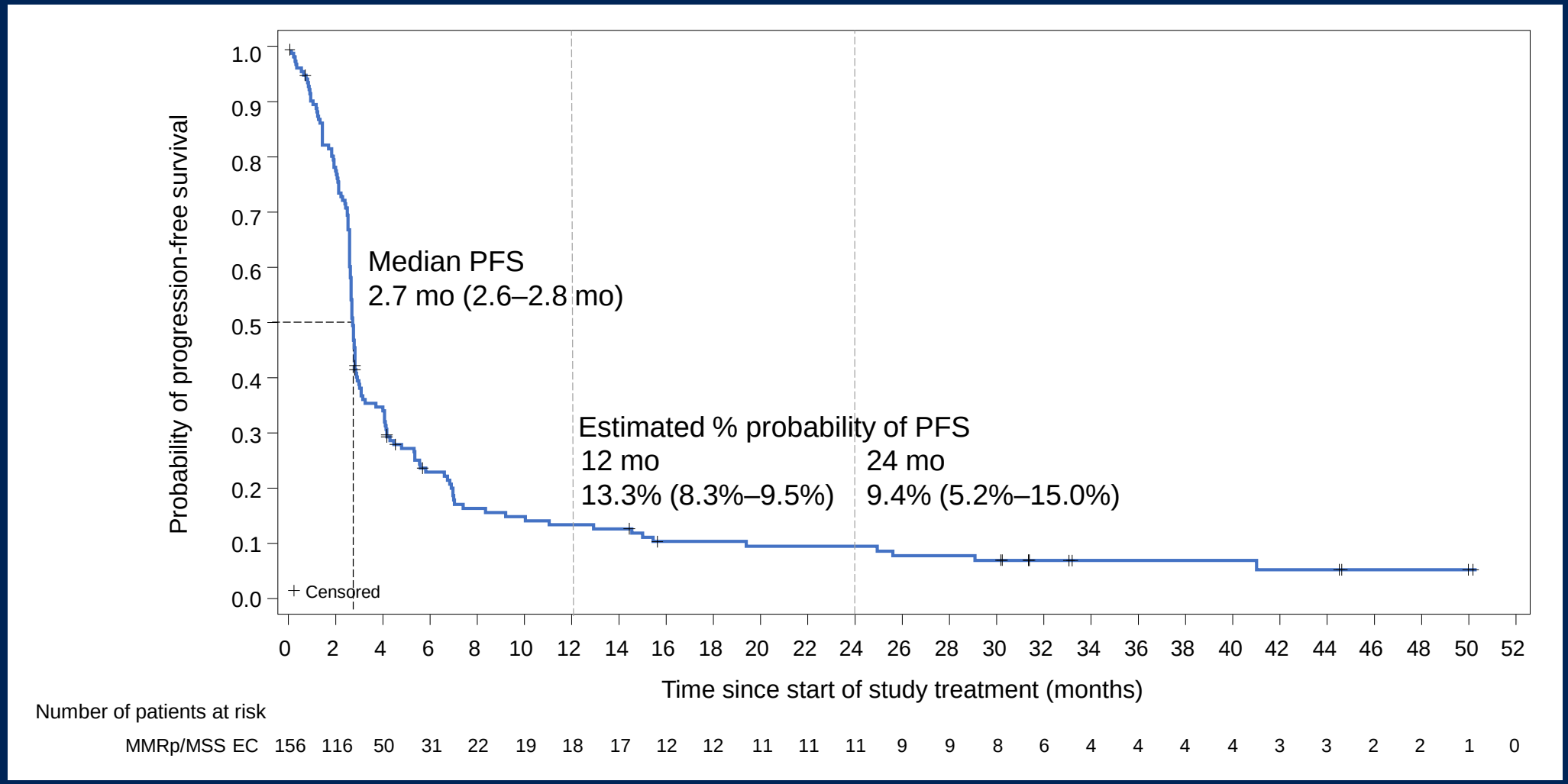
CR, complete response; MMRp, mismatch repair proficient; MSS, microsatellite stable; PD, progressive disease; PR, partial response; SD, stable disease.

Probability of Progression-Free Survival: dMMR/MSI-H



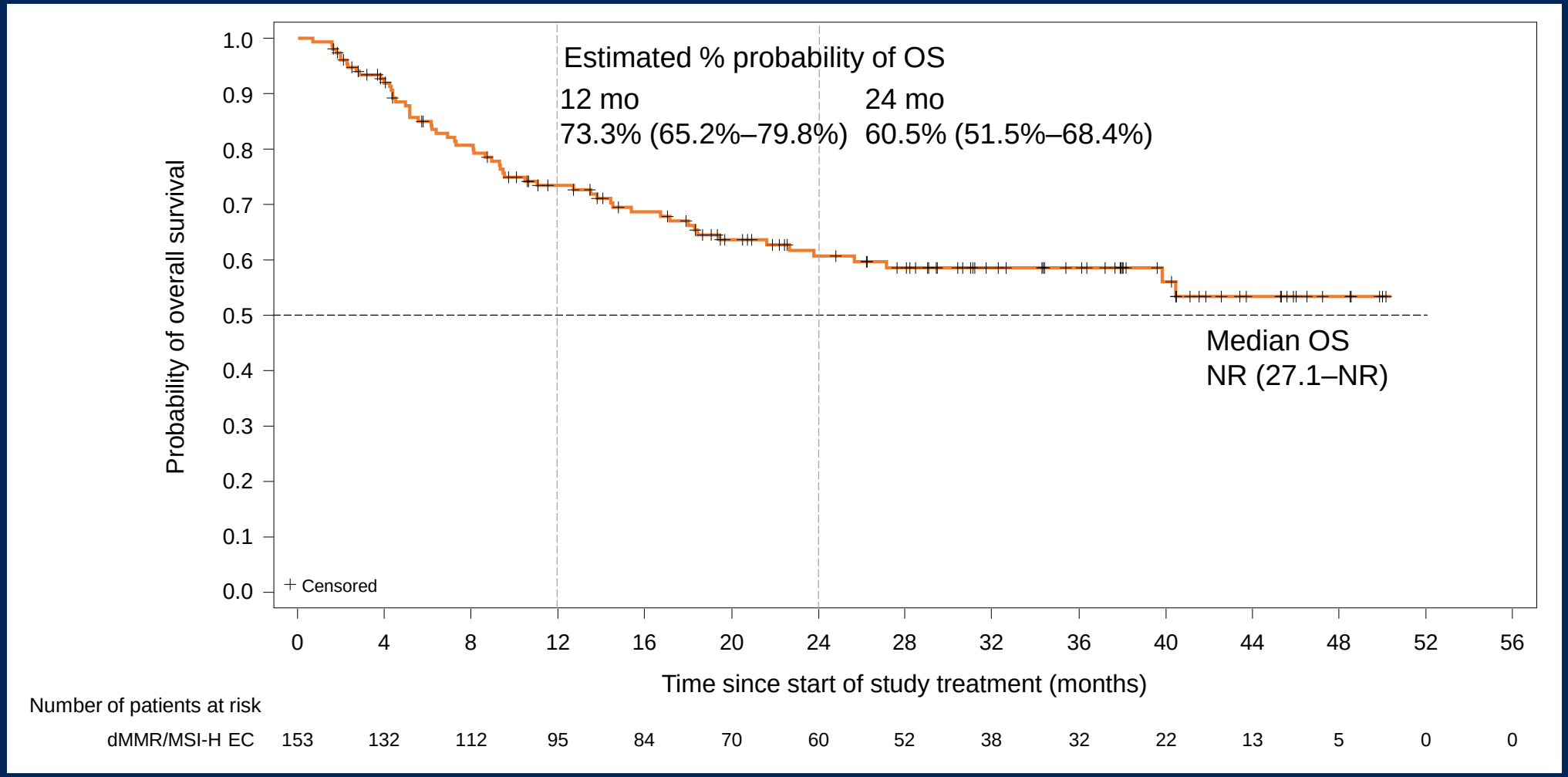
dMMR, mismatch repair deficient; EC, endometrial cancer; MSI-H, microsatellite instability–high; PFS, progression-free survival.

Probability of Progression-Free Survival: MMRp/MSS



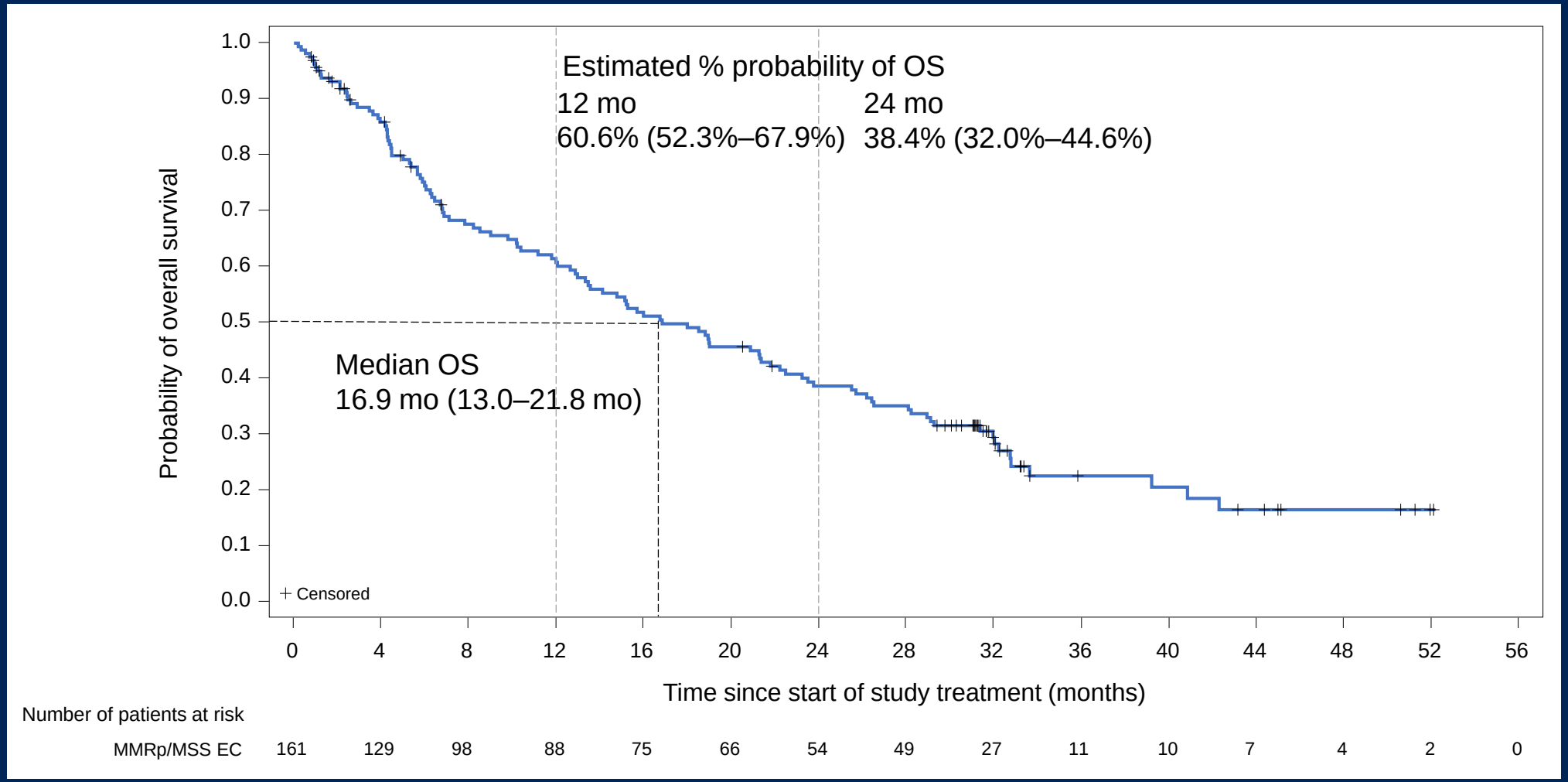
EC, endometrial cancer; MMRp, mismatch repair proficient; MSS, microsatellite stable; PFS, progression-free survival.

Probability of Overall Survival: dMMR/MSI-H



dMMR, mismatch repair deficient; EC, endometrial cancer; MSI-H, microsatellite instability–high; NR, not reached; OS, overall survival.

Probability of Overall Survival: MMRp/MSS



EC, endometrial cancer; MMRp, mismatch repair proficient; MSS, microsatellite stable; OS, overall survival; PFS, progression-free survival.

Safety Summary

- The safety population included all patients with EC who had received ≥1 dose of dostarlimab
- Most TRAEs were grade 1 or 2 and were manageable
- 27 (8.6%) patients discontinued treatment because of a TRAE
- No deaths associated with dostarlimab were reported in these cohorts

Parameter, n (%)	dMMR/MSI-H EC N=153	MMRp/MSS EC N=161	Overall N=314
Any TEAE	152 (99.3)	161 (100)	313 (99.7)
Grade ≥3 TEAE	87 (56.9)	95 (59.0)	182 (58.0)
Any-grade TRAE	108 (70.6)	115 (71.4)	223 (71.0)
Grade ≥3 TRAE	27 (17.6)	33 (20.5)	60 (19.1)
Any irTRAE	42 (27.5)	31 (19.3)	73 (23.2)
Grade ≥3 irTRAE	16 (10.5)	9 (5.6)	25 (8.0)
Treatment-related SAE	18 (11.8)	14 (8.7)	32 (10.2)
Any TRAE leading to discontinuation	13 (8.5)	14 (8.7)	27 (8.6)
TRAE leading to death	0	0	0

dMMR, mismatch repair deficient; EC, endometrial cancer; ir, immune related; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable; OS, overall survival; PFS, progression-free survival; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

Safety

Preferred term, n (%)	dMMR/MSI-H EC N=153	MMRp/MSS EC N=161	Overall N=314
Any-grade TRAEs occurring in ≥10% of patients			
Fatigue	21 (13.7)	35 (21.7)	56 (17.8)
Diarrhea	25 (16.3)	21 (13.0)	46 (14.6)
Nausea	19 (12.4)	24 (14.9)	43 (13.7)
Asthenia	24 (15.7)	13 (8.1)	37 (11.8)
Grade ≥3 TRAEs occurring in ≥1% of patients			
Anemia	7 (4.6)	3 (1.9)	10 (3.2)
Alanine aminotransferase increased	3 (2.0)	3 (1.9)	6 (1.9)
Amylase increased	1 (0.7)	4 (2.5)	5 (1.6)
Diarrhea	3 (2.0)	2 (1.2)	5 (1.6)
Aspartate aminotransferase increased	0	4 (2.5)	4 (1.3)
Fatigue	1 (0.7)	3 (1.9)	4 (1.3)
Hyperglycemia	1 (0.7)	3 (1.9)	4 (1.3)
Lipase increased	3 (2.0)	1 (0.6)	4 (1.3)
Pneumonitis	2 (1.3)	1 (0.6)	3 (1.0)

Preferred term, n (%)	dMMR/MSI-H EC N=153	MMRp/MSS EC N=161	Overall N=314
Grade ≥2 irTRAEs occurring in ≥2% of patients[a]			
Hypothyroidism	13 (8.5)	13 (8.1)	26 (8.3)
Alanine aminotransferase increased	5 (3.3)	3 (1.9)	8 (2.5)
Aspartate aminotransferase increased	2 (1.3)	5 (3.1)	7 (2.2)
Arthralgia	6 (3.9)	4 (2.5)	10 (3.2)
Grade ≥3 irTRAEs occurring in ≥1% of patients			
Alanine aminotransferase increased	3 (2.0)	3 (1.9)	6 (1.9)
Aspartate aminotransferase increased	0	4 (2.5)	4 (1.3)
Pneumonitis	2 (1.3)	1 (0.6)	3 (1.0)
Any-grade TRAE leading to discontinuation in ≥1% of patients			
Alanine aminotransferase increased	2 (1.3)	3 (1.9)	5 (1.6)
Aspartate aminotransferase increased	1 (0.7)	2 (1.2)	3 (1.0)
Pneumonitis	2 (1.3)	1 (0.6)	3 (1.0)

[a]Immune-related AEs were defined as grade 2 and above from a predefined list.

AE, adverse event; dMMR, mismatch repair deficient; EC, endometrial cancer; ir, immune related; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable; TRAE, treatment-related adverse event.

Conclusions

- Dostarlimab demonstrated durable antitumor activity in both dMMR/MSI-H and MMRp/MSS advanced or recurrent EC
  - Median follow-up time is 27.6 (dMMR/MSI-H) and 33.0 (MMRp/MSS) months
- Cohort A1 is the largest cohort of patients with dMMR/MSI-H EC studied with an anti–PD-1 monotherapy to date
  - The probability of remaining in response at 24 months was 83.7%
- Dostarlimab is the only PD-1 therapy clinically tested with a Q6W dosing schedule in endometrial cancer
  - The safety profile was manageable
  - The majority of TRAEs were grade 1 or 2
  - Discontinuation rates were low
    - 8.6% of patients discontinued treatment because of a TRAE

AE, adverse event; dMMR, mismatch repair deficient; EC, endometrial cancer; ir, immune related; MMRp, mismatch repair proficient; MSI-H, microsatellite instability–high; MSS, microsatellite stable; PD-1, programmed death 1; TRAE, treatment-related adverse event; Q6W, every 6 weeks.

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