Ana Oaknin

AIMING TO IMPROVE FIRST-LINE THERAPY OUTCOMES: ADDING ANTI-PD-1(L1)TO PACLITAXEL/CARBOPLATIN

Phase 3 Trials

Newly diagnosed Stage III/Stage IV or recurrent EC. N=699 MSI status: Stratification factor	**GOG-3041/ENGOT-EN11/DUO-E/** **NCT04269200**	A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination With Durvalumab, Followed by Maintenance **Durvalumab With or Without Olaparib** in Patients With Newly Diagnosed Advanced or Recurrent Endometrial Cancer
Stage III/IV with residual disease or recurrent endometrial cancer. N=550 MSI status: Stratification factor	**Attend/ ENGOT-EN7** **NCT03603184**	Phase III Double-blind Randomized Placebo Controlled Trial of **Atezolizumab** in Combination With Paclitaxel and Carboplatin in Women With Advanced/Recurrent Endometrial Cancer
Stage III/IV or recurrent endometrial cancer (Stage II or IVA: measurable disease; Stage IVB or recurrent whether there is measurable disease or not) N = 590 pMMR patients N = 220 dMMR patients	**NRG-GY-018** **NCT03914612**	Testing the Addition of the Immunotherapy Drug **Pembrolizumab** to the Usual Chemotherapy Treatment (Paclitaxel and Carboplatin) in Stage III-IV or Recurrent Endometrial Cancer
Recurrent or primary advanced (Stage III or IV) endometrial cancer Part 1 N = 470 **Part 2 N = 270**	**GOG-3031/ENGOT-EN6/RUBY** **NCT03981796**	A Phase 3, Randomized, Double-blind, Multicenter Study of **Dostarlimab With or Without Niraparib** Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer

Mansoor R. Mirza

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DOSTARLIMAB IN COMBINATION WITH CHEMOTHERAPY FOR THE TREATMENT OF PRIMARY ADVANCED OR RECURRENT ENDOMETRIAL CANCER: A PLACEBO-CONTROLLED RANDOMIZED PHASE 3 TRIAL (ENGOT-EN6-NSGO/GOG-3031/RUBY)

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FINANCIAL DISCLOSURES

Dr Mirza reports consulting or advisory role at AstraZeneca, Biocad, GSK, Karyopharm, Merck, Roche, Zailab; speakers' bureau fees from AstraZeneca and GSK; research funding (to institution) from Apexigen, AstraZeneca, Deciphera (trial chair), GSK, and Ultimovacs; and personal financial interest in Karyopharm (stocks/shares, member of Board of Directors)

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Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancers: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

Mansoor R. Mirza

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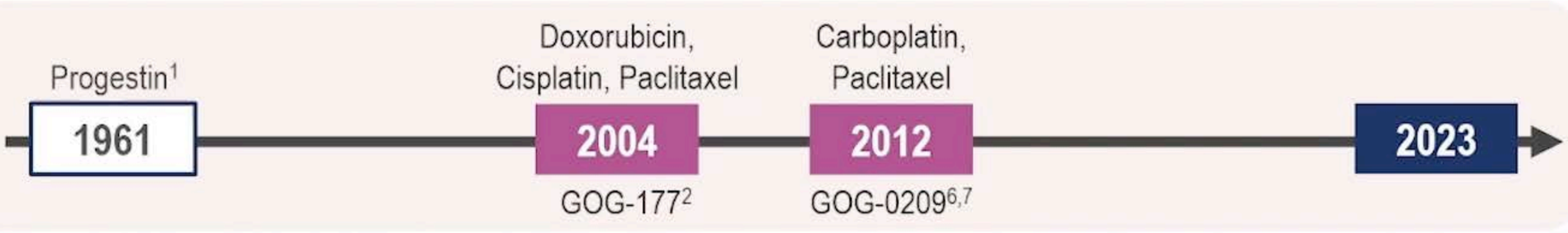
BACKGROUND

- Carboplatin/paclitaxel (CP) is standard of care for first-line treatment of primary advanced or recurrent EC; however long-term outcomes remain poor, with median OS <3 years[1,2]
- Anti–PD-1 based therapy has transformed the management of EC post-platinum chemotherapy[3-5]
- Advances in first-line systemic treatment are urgently needed



CP, carboplatin-paclitaxel; EC, endometrial cancer; OS, overall survival.
1. Yang S, et al. *Discov Med*. 2011;12:205-212. 2. Fleming GF, et al. *J Clin Oncol*. 2004;22:2159-2166. 3. Oaknin A, et al. *J Immunother Cancer*. 2022;10(1):e003777. 4. O'Malley DM, et al. *J Clin Oncol*. 2022;40(7):752-761. 5. Makker V, et al. *N Engl J Med*. 2022;386:437-448 6. Miller DS, et al., *Gynecol Oncol*. 2012;125:771–773. 7. Miller DS, et al., *J Clin Oncol*. 2020;38:3841-3850

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STUDY RATIONALE

Dostarlimab +

- Durable activity in both dMMR/MSI-H and MMRp/MSS previously treated EC[1]
- dMMR/MSI-H EC is associated with:
  - High TMB/TILs[2]
  - Higher response rate to anti–PD-1[1]

Chemotherapy

- Enhances immunogenic cell-death[3,4]
- Reduces immunosuppression in TME[3,4]
- Broad clinical activity when combined with anti–PD-1 in several cancers[5–8]

Study Hypothesis

Dostarlimab + CP will improve outcomes in the **dMMR/MSI-H** and **overall** primary advanced or recurrent EC patient populations vs CP alone

CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; EC, endometrial cancer; MMRp, mismatch repair proficient; MSI-H, microsatellite instability-high; MSS, microsatellite stable; PD-1, programmed death protein-1; TIL, tumor infiltrating lymphocytes; TMB, tumor mutational burden; TME, tumor microenvironment.

1. Oaknin A, Gilbert L, Tinker AV, et al. *J Immunother Cancer*. 2022;10:e003777. 2. Song Y, et al. *Onco Targets Ther*. 2021;14:4485-4497. 3. Emens LA, Middleton G. *Cancer Immunol*. 2015;3(5):436-443. 4. Hato SV, et al. *Clin Cancer Res*. 2014;20:2831-2837. 5. Gandhi L, et al. *N Engl J Med*. 2018;378:2078-92. 6. Paz-Ares L, et al. *N Engl J Med*. 2018;379:2040-51. 7. Janjigian YY, et al. *Lancet*. 2021;398:27-40. 8. Burtness B, et al. *Lancet*. 2019;394:1915-1928.

Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancers: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

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ENGOT-EN6-NSGO/GOG-3031/RUBY (NCT03981796)

Phase 3, randomized, double-blind, multicenter study of dostarlimab plus carboplatin-paclitaxel versus placebo plus carboplatin/paclitaxel in patients with primary advanced or recurrent EC

Eligible patients

- Histologically/cytologically proven advanced or recurrent EC
- Stage III/IV disease or first recurrent EC with low potential for cure by radiation therapy or surgery alone or in combination
  - Carcinosarcoma, clear cell, serous, or mixed histology permitted[a]
- Naïve to systemic therapy or systemic anticancer therapy and had a recurrence or PD ≥6 months after completing treatment
- ECOG PS 0-1
- Adequate organ function

Stratification

- MMR/MSI status[b]
- Prior external pelvic radiotherapy
- Disease status

R1:1

Dostarlimab IV 500 mg
Carboplatin AUC 5 mg/mL/min
Paclitaxel 175 mg/m^2
Q3W for 6 cycles

→ **Dostarlimab IV** 1000 mg Q6W up to 3 years[c]

Placebo
Carboplatin AUC 5 mg/mL/min
Paclitaxel 175 mg/m^2
Q3W for 6 cycles

→ **Placebo IV** Q6W up to 3 years[c]

→ Follow-up

Primary endpoint

- PFS by INV
- OS

Secondary endpoints

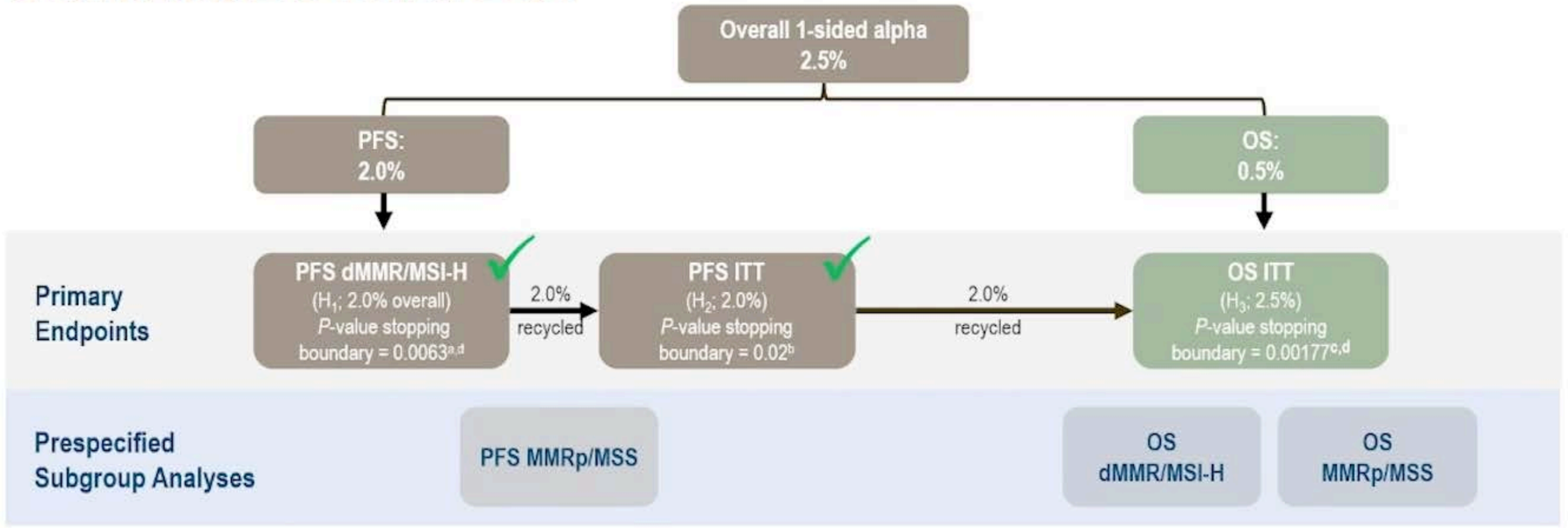
- PFS by BICR
- PFS2
- ORR
- DOR
- DCR
- HRQOL/PRO
- Safety

On-study imaging assessments are to be performed Q6W (±7 days) from the randomization date until Week 25 (Cycle 8), followed by Q9W (±7 days) until Week 52. Subsequent tumor imaging is to be performed every 12 weeks (±7 days) until radiographic PD is documented by investigator assessment per RECIST v1.1 followed by one additional imaging 4-6 weeks later,or subsequent anticancer therapy is started, whichever occurs first. Thereafter, scans may be performed per standard of care.

[a]Mixed histology containing at least 10% carcinosarcoma, clear cell, or serous histology. [b]Patients were randomized based on either local or central MMR/MSI testing results. Central testing was used with local results were not available. For local determination of MMR/MSI status, IHC, next generation sequencing, and polymerase chain reaction assays were accepted. For central determination of MMR/MSI status IHC per Ventana MMR RxDx panel was used. [c]Treatment ends after 3 years, PD, toxicity, withdrawal of consent, investigator's decision, or death, whichever occurs first. Continued treatment with dostarlimab or placebo beyond 3 years may be considered following discussion between the Sponsor and the Investigator. AUC, area under the plasma or serum concentration-time curve; BICR, blinded independent central review; DCR, disease control rate; DOR, duration of response; EC, endometrial cancer; IV, administered intravenously; INV, investigator assessment; MMR, mismatch repair; MSI, microsatellite instability; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome.

Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancer: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

STATISTICAL TESTING AND MULTIPLICITY CONTROL STRATEGY



Multiplicity control strategy is based on the graphical method (Maurer, 2013)
[a] Hypothesis for PFS dMMR/MSI (H_1) was tested at the IA with 0.63% alpha spent from the overall alpha level (2.0%) initially allocated. [b] Since null hypothesis (H_{01}) for H_1 was rejected at IA, the 2.0% alpha for (H_1) was recycled to hypothesis testing of PFS ITT (H_2). H_2 was tested at alpha level (2.0%)= 2.0% recycled + 0% initially allocated. [c] Since both null hypotheses (H_{02} and H_{03}) were rejected, 2.0% alpha for the family of hypothesis testing of PFS was recycled to testing of OS (H_3). H_3 was tested at alpha level (2.5%)= 2.0% recycled + 0.5% initially allocated. [d] Stopping boundaries and alpha spent at IA were adjusted based on the actual number of events/information fraction observed based on the prespecified alpha spending function at the time of analysis; *P*-value stopping boundary (IA)= 0.0063 for PFS dMMR/MSI-H; *P* value stopping boundary (IA1)=0.00177 for OS ITT. [e] Not formally tested.
dMMR, mismatch repair deficient; FA, final analysis; H, hypothesis; IA, interim analysis; ITT, intent to treat; MMRp, mismatch repair proficient; MSI-H, microsatellite instability-high; MSS, microsatellite stable; OS, overall survival; PFS, progression-free survival.

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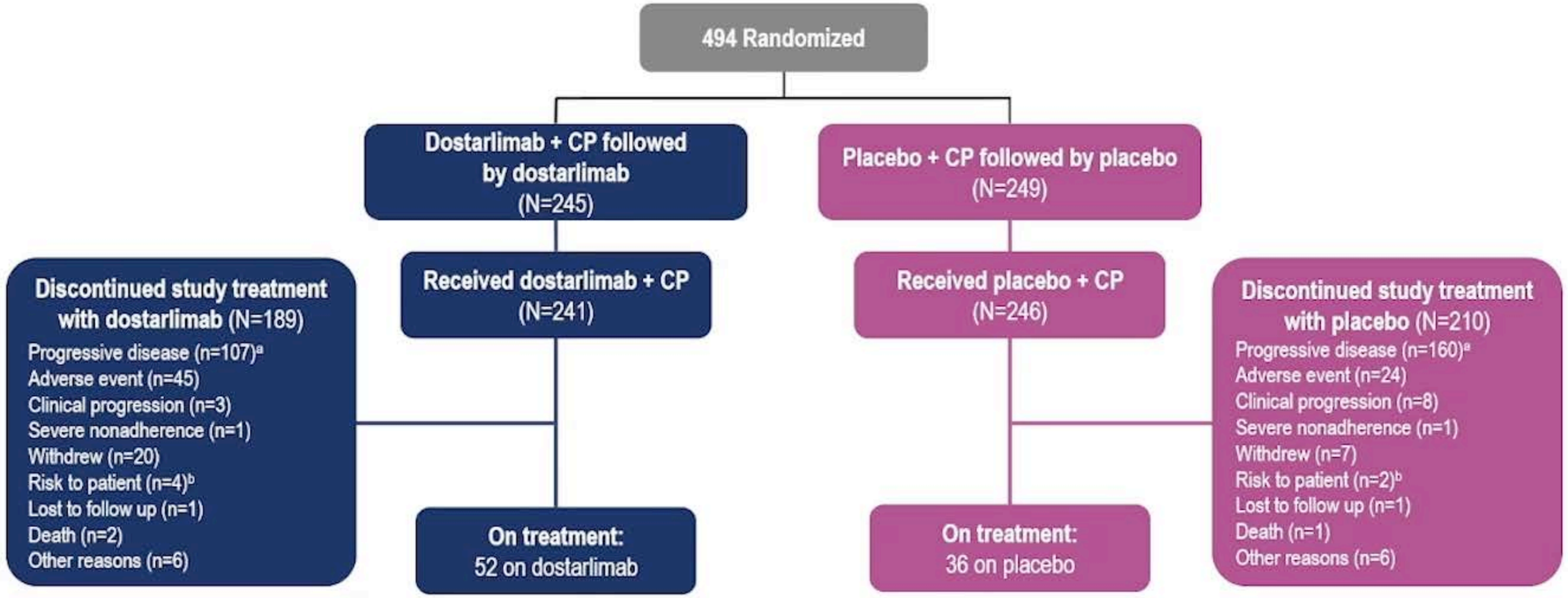
PATIENT DISPOSITION



Data cutoff date: September 28, 2022.
aProgressive disease according to RECIST v1.1 by the investigator, sponsor, or both. bRisk to patient as judged by the investigator, sponsor, or both.
CP, carboplatin/paclitaxel.

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PATIENT POPULATION AND BASELINE CHARACTERISTICS

Variable, n (%)	dMMR/MSI-H		Overall	
	Dostarlimab + CP (N=53)	Placebo + CP (N=65)	Dostarlimab + CP (N=245)	Placebo + CP (N=249)
MMR/MSI status				
dMMR/MSI-H	53 (100)	65 (100)	53 (21.6)	65 (26.1)
MMRp/MSS	—	—	192 (78.4)	184 (73.9)
Prior external pelvic radiation				
Yes	8 (15.1)	13 (20.0)	41 (16.7)	45 (18.1)
No	45 (84.9)	52 (80.0)	204 (83.3)	204 (81.9)
Disease status				
Primary stage III	10 (18.9)	14 (21.5)	45 (18.4)	47 (18.9)
Primary stage IV	16 (30.2)	19 (29.2)	83 (33.9)	83 (33.3)
Recurrent	27 (50.9)	32 (49.2)	117 (47.8)	119 (47.8)

CP, carboplatin/paclitaxel; dMMR, mismatch repair deficient; MMR, mismatch repair; MMRp, mismatch repair proficient; MSI, microsatellite instability; MSI-H, microsatellite instability-high; MSS, microsatellite stable

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BASELINE CHARACTERISTICS

Variable, n (%)	dMMR/MSI-H		Overall	
	Dostarlimab + CP (N=53)	Placebo + CP (N=65)	Dostarlimab + CP (N=245)	Placebo + CP (N=249)
Age				
Median age, yr (range)	61 (45–81)	66 (39–85)	64 (41–81)	65 (28–85)
≥65	23 (43.4)	35 (53.8)	118 (48.2)	135 (54.2)
Race				
White	44 (83.0)	56 (86.2)	189 (77.1)	191 (76.7)
Black	4 (7.5)	6 (9.2)	28 (11.4)	31 (12.4)
Asian	2 (3.8)	0	7 (2.9)	8 (3.2)
Other[a]	3 (5.7)	3 (4.6)	21 (8.6)	19 (7.6)
ECOG[b]				
0	28 (53.8)	39 (60.0)	145 (60.2)	160 (65.0)
1	24 (46.2)	26 (40.0)	96 (39.8)	86 (35.0)
BMI				
Median BMI (range)	30.6 (20.1-54.4)	35.5 (17.9-58.1)	30.8 (17.6-60.6)	32.8 (17.7-68.0)
Measurable disease at baseline				
Yes	49 (92.5)	58 (89.2)	212 (86.5)	219 (88.0)
No	4 (7.5)	7 (10.8)	33 (13.5)	30 (12.0)

Variable, n (%)	dMMR/MSI-H		Overall	
	Dostarlimab + CP (N=53)	Placebo + CP (N=65)	Dostarlimab + CP (N=245)	Placebo + CP (N=249)
Prior Anticancer Treatment				
Yes	7 (13.2)	10 (15.4)	48 (19.6)	52 (20.9)
Carboplatin/ paclitaxel	4 (7.5)	6 (9.2)	36 (14.7)	39 (15.7)
Histology type				
Carcinosarcoma	4 (7.5)	1 (1.5)	25 (10.2)	19 (7.6)
Endometrioid	44 (83.0)	56 (86.2)	134 (54.7)	136 (54.6)
Mixed carcinoma[b]	2 (3.8)	4 (6.2)	10 (4.1)	9 (3.6)
Serous adenocarcinoma	1 (1.9)	1 (1.5)	50 (20.4)	52 (20.9)
Clear cell adenocarcinoma	0	0	8 (3.3)	9 (3.6)
Mucinous adenocarcinoma	0	0	0	1 (0.4)
Undifferentiated carcinoma	0	0	1 (0.4)	2 (0.8)
Other	2 (3.8)	3 (4.6)	17 (6.9)	21 (8.4)

[a]Other includes patients identifying as American Indian or Alaska native, native Hawaiian or other Pacific Islander, unknown, or not reported. [b]Patients with ECOG score: 52 dostarlimab+CP dMMR/MSI-H, 65 placebo+CP dMMR/MSI-H, 241 dostarlimab+CP overall, 246 placebo+CP overall. [b]Mixed carcinoma ≥10% of carcinosarcoma, clear cell, or serous histology.
BMI, body mass index; CP, carboplatin/paclitaxel; dMMR, mismatch repair deficient; ECOG, Eastern Cooperative Oncology Group; MSI-H, microsatellite instability-high.

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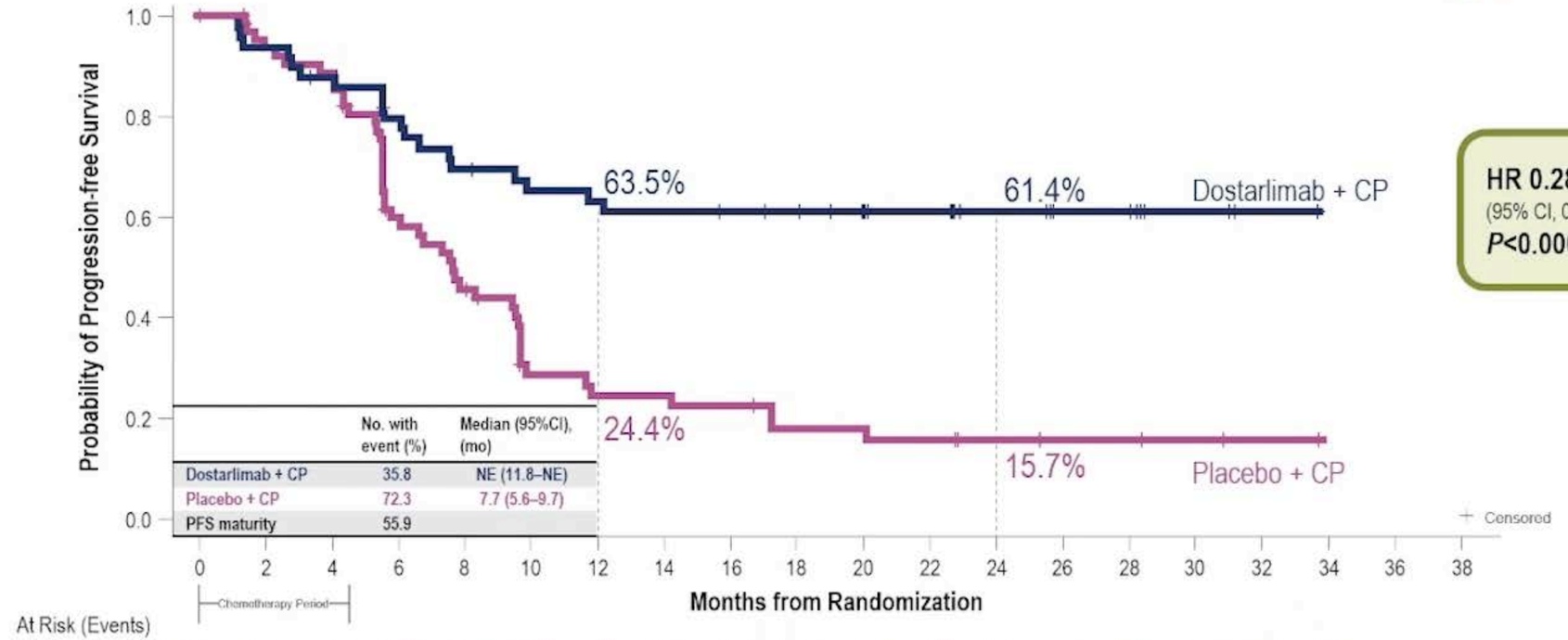
PRIMARY ENDPOINT: PFS IN dMMR/MSI-H POPULATION



HR 0.28
(95% CI, 0.162–0.495)
P<0.0001

*Median duration of follow-up 24.79 months
CP, carboplatin/paclitaxel; dMMR, mismatch repair deficient; HR, hazard ratio; MSI-H, microsatellite instability-high; NE, not estimable; PFS, progression-free survival.

Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancer: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

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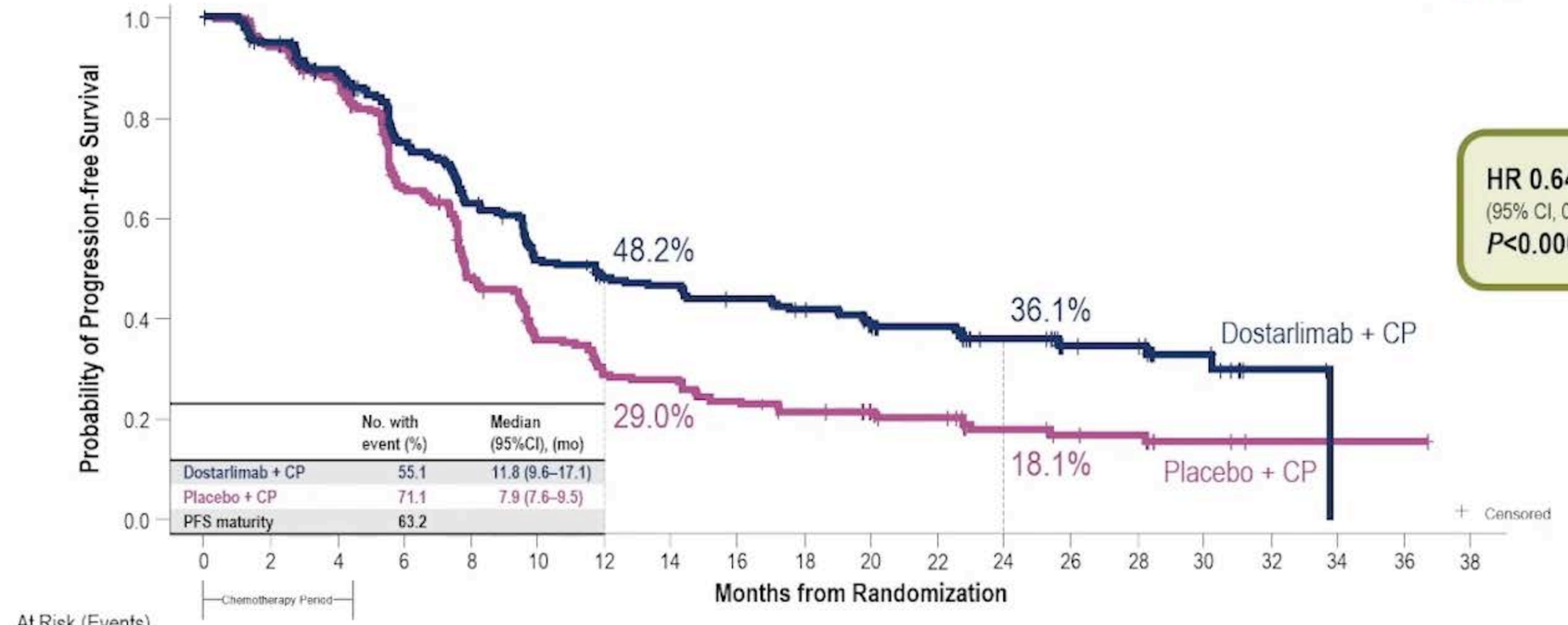
PRIMARY ENDPOINT: PFS IN OVERALL POPULATION



HR 0.64
(95% CI, 0.507–0.800)
P<0.0001

[a]Median duration of follow-up 25.38 months.
CP, carboplatin/paclitaxel; HR, hazard ratio; PFS, progression-free survival

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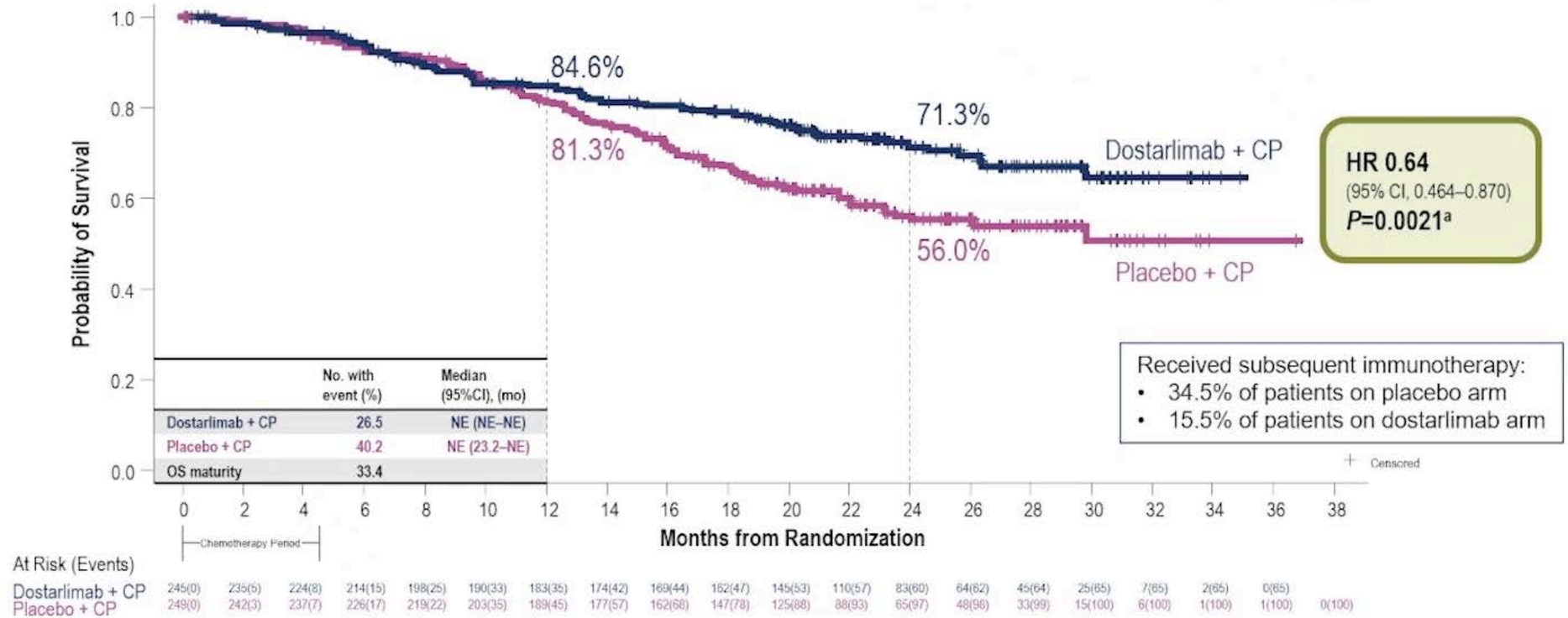
PRIMARY ENDPOINT: OS IN OVERALL POPULATION (33% MATURITY)



Median duration of follow-up 25.38 months
[a]P≤0.00177 required to declare statistical significance at first interim analysis.
CP, carboplatin/paclitaxel; HR, hazard ratio; NE, not estimable; OS, overall survival.

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ENGOT-EN6-NSGO/GOG-3031/RUBY presented by Mansoor R Mirza

Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancer: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

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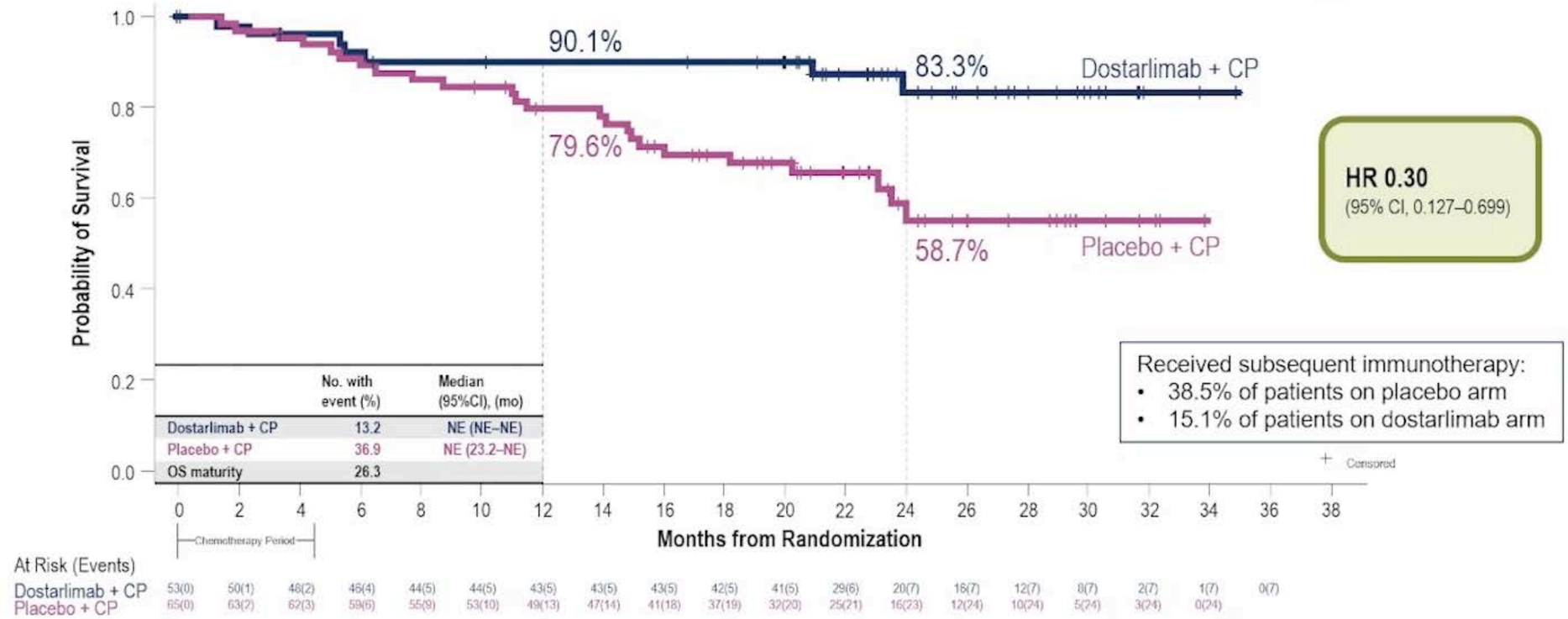
OS IN dMMR/MSI-H POPULATION



CP, carboplatin/paclitaxel; dMMR, mismatch repair deficient; HR, hazard ratio; MSI-H, microsatellite instability-high; NE, not estimable; OS, overall survival.

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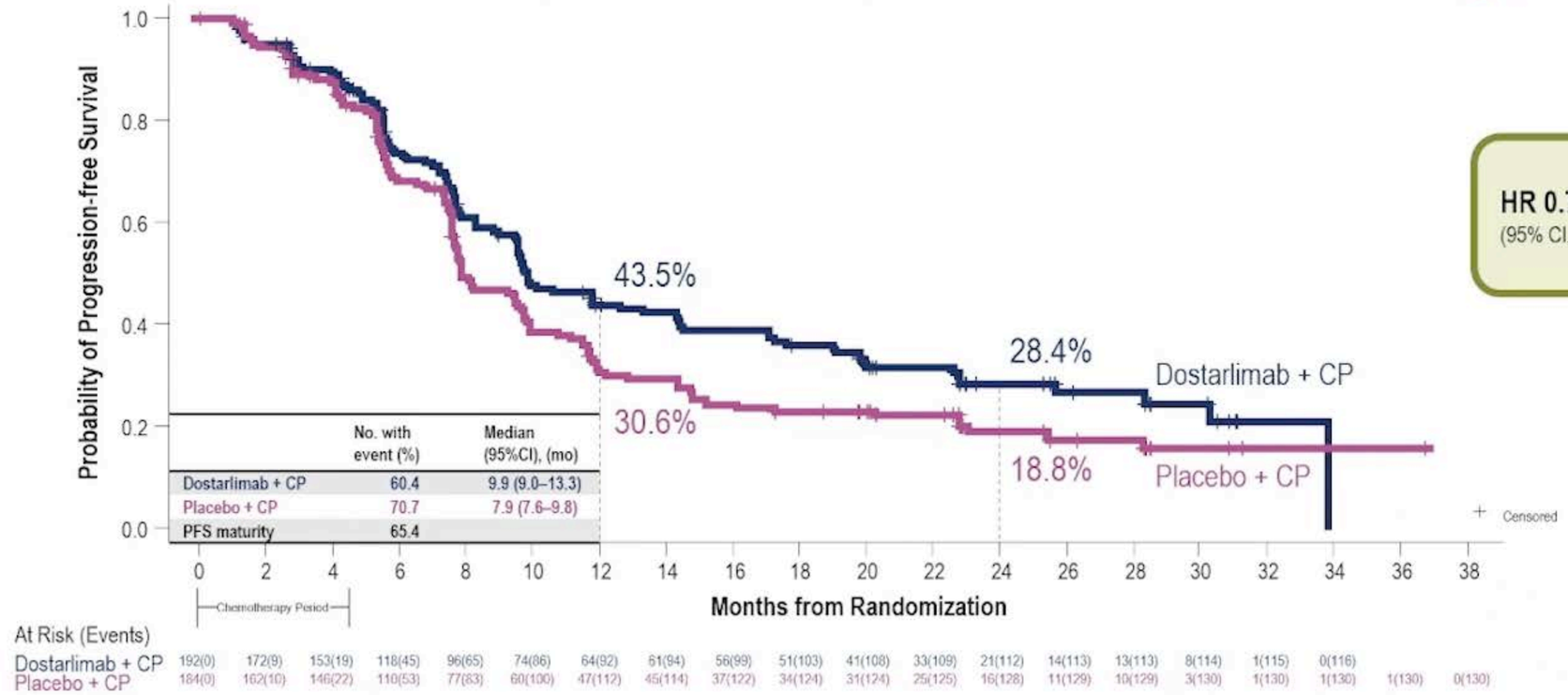
PFS IN MMRp/MSS POPULATION



HR 0.76
(95% CI, 0.592–0.981)

CP, carboplatin/paclitaxel; HR, hazard ratio; MMRp, mismatch repair proficient; MSS, microsatellite stable; PFS, progression-free survival.

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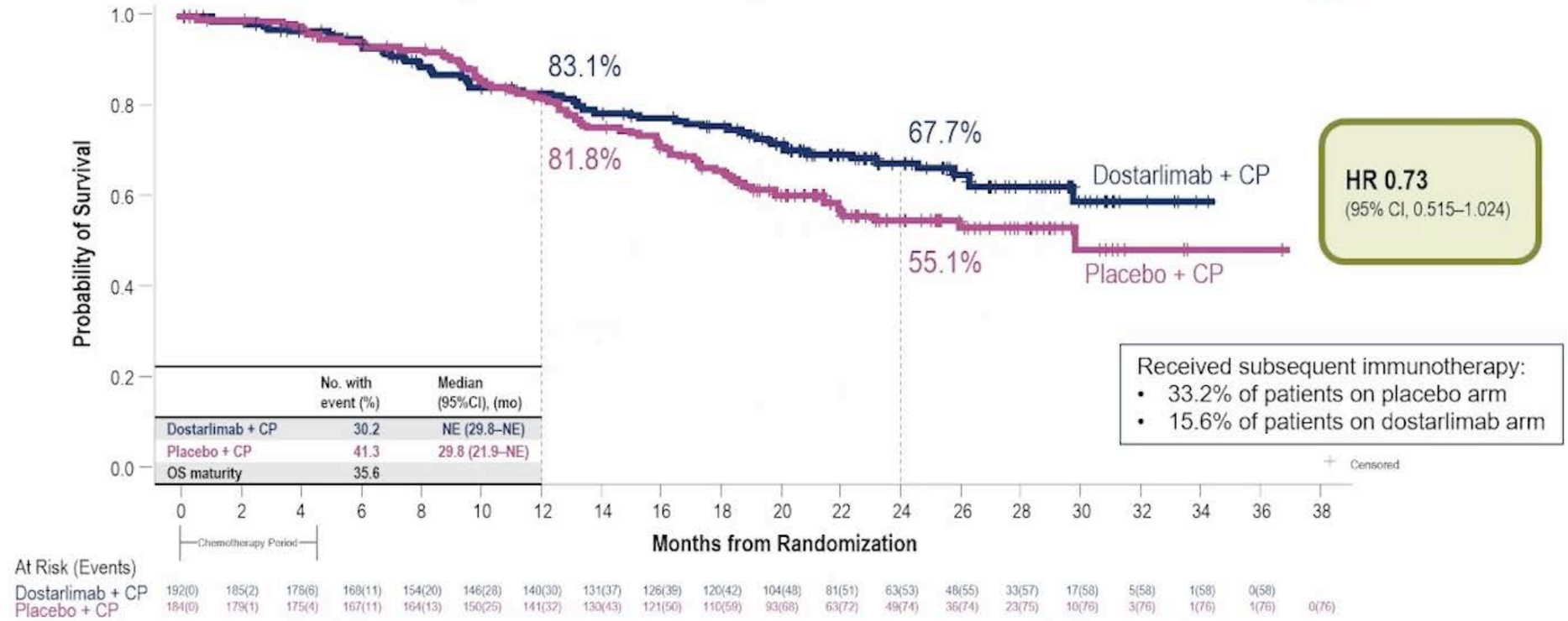
OS IN MMRp/MSS POPULATION



Received subsequent immunotherapy:
- 33.2% of patients on placebo arm
- 15.6% of patients on dostarlimab arm

CP, carboplatin/paclitaxel; HR, hazard ratio; MMRp, mismatch repair proficient; MSS, microsatellite stable; NE, not estimable; OS, overall survival.

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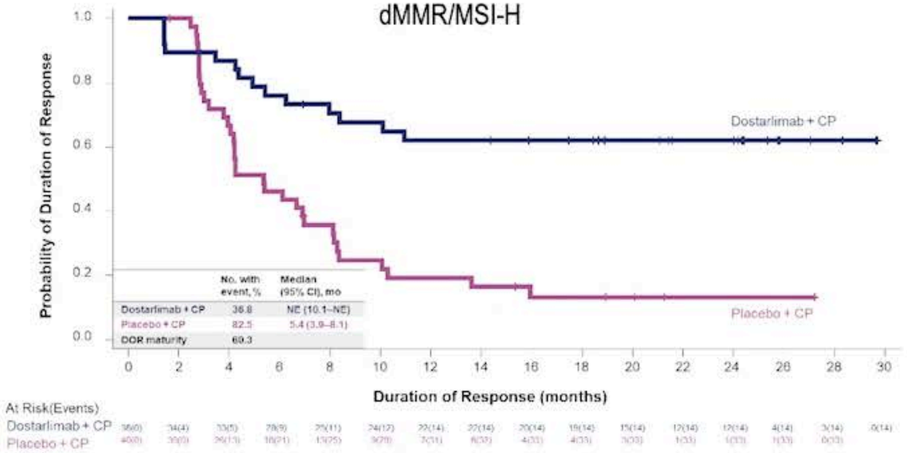
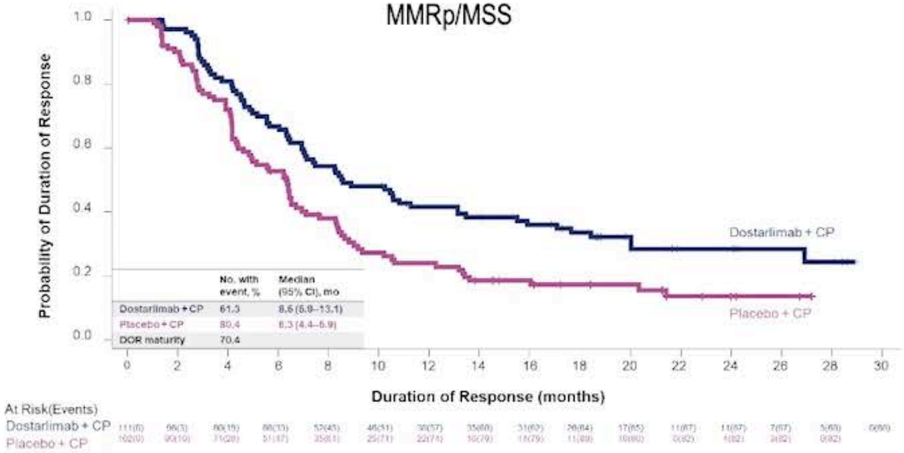
OBJECTIVE RESPONSE RATE AND DURATION OF RESPONSE

	dMMR/MSI-H	
	Dostarlimab + CP (N=53)	Placebo + CP (N=65)
ORR, %[a] (n/N; 95% CI)	**77.6** (38/49; 63.4–88.2)	**69.0** (40/58; 55.5–80.5)
CR	15 (30.6)	12 (20.7)
PR	23 (46.9)	28 (48.3)

	MMRp/MSS	
	Dostarlimab + CP (N=192)	Placebo + CP (N=184)
ORR, %[a] (n/N; 95% CI)	**68.1** (111/163; 60.4–75.2)	**63.4** (102/161; 55.4–70.8)
CR	38 (23.3)	31 (19.3)
PR	73 (44.8)	71 (44.1)

Duration of Response[b]





[a]ORR based on patients with evaluable disease at baseline in the dMMR/MSI-H and MMRp/MSS populations were prespecified analyses. [b]DOR in the dMMR/MSI-H population was a prespecified analysis and in the MMRp/MSS population was a post hoc analysis.
CP, carboplatin/paclitaxel; CR, complete response; dMMR, mismatch repair deficient; DOR, duration of response; MMRp, mismatch repair proficient; MSI-H, microsatellite instability-high; MSS, microsatellite stable; ORR, objective response rate; PR, partial response.

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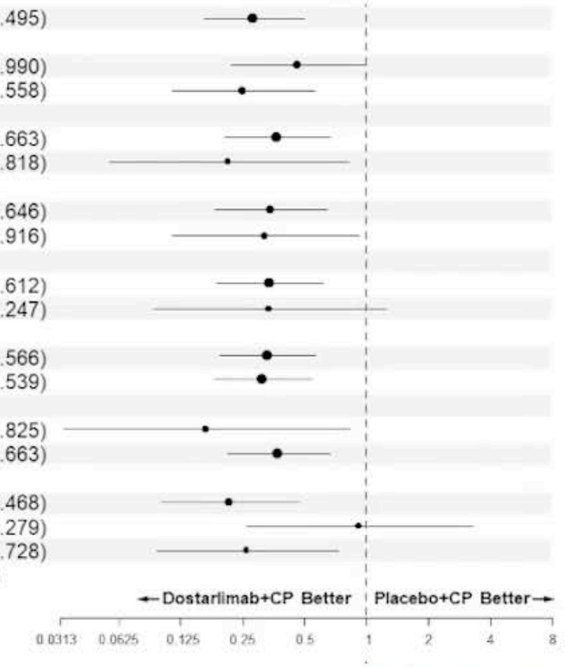
SUBGROUP ANALYSIS OF PROGRESSION-FREE SURVIVAL IN dMMR/MSI-H POPULATION

Categories	Dostarlimab + Carboplatin/Paclitaxel (no. of events/no. of patients)	Placebo + Carboplatin/Paclitaxel (no. of events/no. of patients)	Hazard Ratio (95% CI)
All patients	19/53	47/65	0.28 (0.162–0.495)
Age			
<65 yr	11/30	18/30	0.46 (0.217–0.990)
≥65 yr	8/23	29/35	0.25 (0.113–0.558)
Race			
White	16/44	38/56	0.37 (0.203–0.663)
Other	3/9	9/9	0.21 (0.055–0.818)
Region			
North America	14/36	35/50	0.34 (0.182–0.646)
Europe	5/17	12/15	0.32 (0.112–0.916)
Histology category			
Endometrioid carcinoma	16/45	37/54	0.34 (0.186–0.612)
Other	3/8	10/11	0.34 (0.092–1.247)
MMR/MSI status			
dMMR/MSI-H	19/53	47/65	0.33 (0.192–0.566)
dMMR status (derived)	19/53	47/63	0.31 (0.182–0.539)
Prior external pelvic radiotherapy			
Yes	2/8	8/13	0.17 (0.034–0.825)
No	17/45	39/52	0.37 (0.209–0.663)
Disease status			
Recurrent	10/27	25/32	0.22 (0.099–0.468)
Primary stage III	4/10	6/14	0.92 (0.260–3.279)
Primary stage IV	5/16	16/19	0.26 (0.095–0.728)
No disease at baseline	0/4	4/7	Not applicable



Hazard ratios for "all subjects" are based on stratified Cox regression model. Hazard ratios for all other subgroups are based on unstratified Cox regression model.
dMMR, mismatch repair deficient; MMRp, mismatch repair proficient; MSI-H, microsatellite instability high; MSS, microsatellite stable; yr, year.

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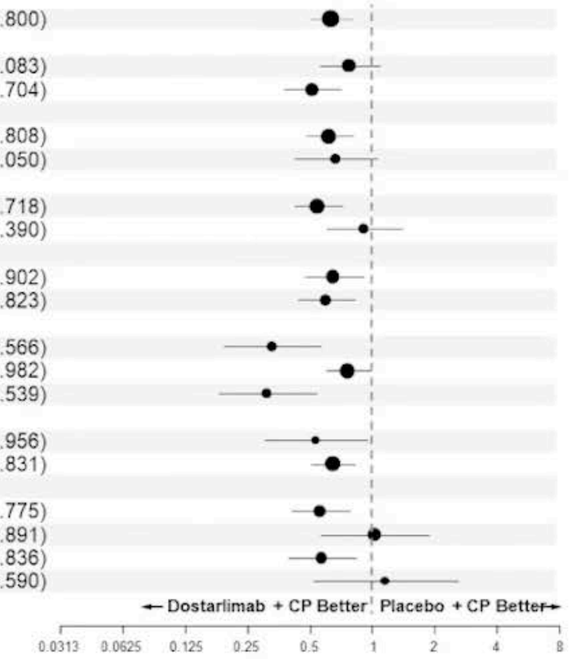
SUBGROUP ANALYSIS OF PROGRESSION-FREE SURVIVAL IN OVERALL POPULATION

Categories	Dostarlimab + Carboplatin/Paclitaxel (no. of events/no. of patients)	Placebo + Carboplatin/Paclitaxel (no. of events/no. of patients)	Hazard Ratio (95% CI)
All patients	135/245	177/249	0.64 (0.507–0.800)
Age			
<65 yr	69/127	72/114	0.78 (0.559–1.083)
≥65 yr	66/118	105/135	0.51 (0.376–0.704)
Race			
White	101/189	135/191	0.62 (0.481–0.808)
Other	34/56	42/58	0.67 (0.422–1.050)
Region			
North America	91/171	133/187	0.55 (0.419–0.718)
Europe	44/74	44/62	0.91 (0.602–1.390)
Histology category			
Endometrioid carcinoma	64/130	89/136	0.65 (0.473–0.902)
Other	71/115	88/113	0.60 (0.439–0.823)
MMR/MSI status			
dMMR/MSI-H	19/53	47/65	0.33 (0.192–0.566)
MMRp/MSS	116/192	130/184	0.76 (0.595–0.982)
dMMR status (derived)	19/53	47/63	0.31 (0.182–0.539)
Prior external pelvic radiotherapy			
Yes	21/41	31/45	0.54 (0.303–0.956)
No	114/204	146/204	0.65 (0.508–0.831)
Disease status			
Recurrent	68/117	89/119	0.56 (0.408–0.775)
Primary stage III	21/45	21/47	1.03 (0.563–1.891)
Primary stage IV	46/83	67/83	0.57 (0.392–0.836)
No disease at baseline	12/33	12/30	1.16 (0.520–2.590)



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SAFETY SUMMARY

Parameter, n (%)	Dostarlimab + CP (N=241)	Placebo + CP (N=246)
Any TEAE	241 (100)	246 (100)
Any grade ≥3 TEAE	170 (70.5)	147 (59.8)
Serious TEAE	91 (37.8)	68 (27.6)
Any treatment-related irAE	92 (38.2)	38 (15.4)
Any TEAE leading to discontinuation of dostarlimab or placebo	42 (17.4)	23 (9.3)
Any TEAE leading to discontinuation of carboplatin	24 (10.0)	19 (7.7)
Any TEAE leading to discontinuation of paclitaxel	24 (10.0)	23 (9.3)
Any TEAE leading to death	5 (2.1)[a]	0
Any TEAE related to dostarlimab leading to death	2 (0.8)[b]	—
Median duration of overall treatment, (range) weeks	43.0 (3.0–150.9)	36.0 (2.1–165.1)

[a]3 deaths were not related to study treatment (opiate overdose, COVID-19, and general physical health deterioration). [b]One death was considered by the investigator as related to dostarlimab plus CP and occurred during the first 6 cycles (myelosuppression); one death was related to dostarlimab and occurred during the 90-day safety follow-up (hypovolemic shock)
CP, carboplatin/paclitaxel; irAE, immune-related adverse event; TEAE, treatment emergent adverse event.

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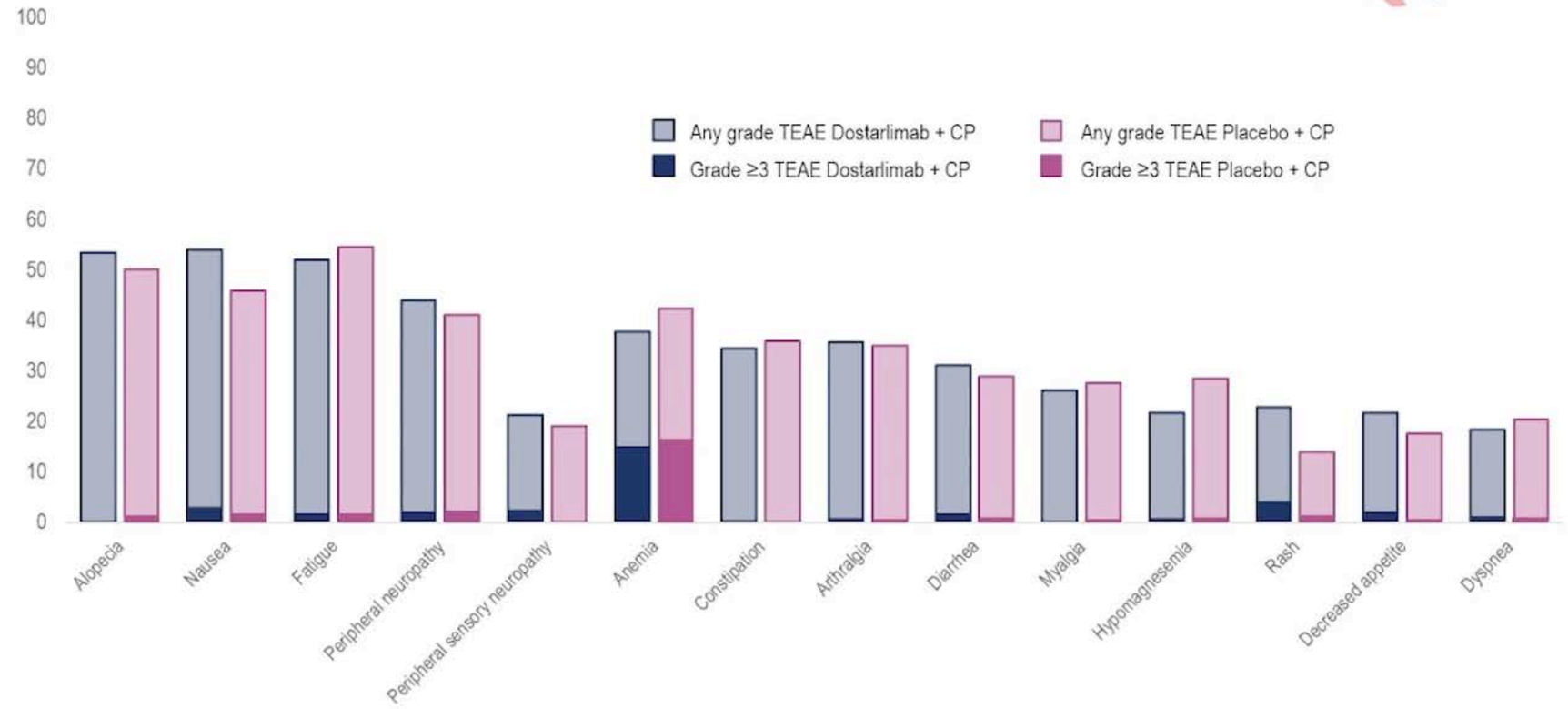
TEAEs IN ≥20% OF EITHER ARM



CP, carboplatin/paclitaxel; TEAE, treatment emergent adverse event.

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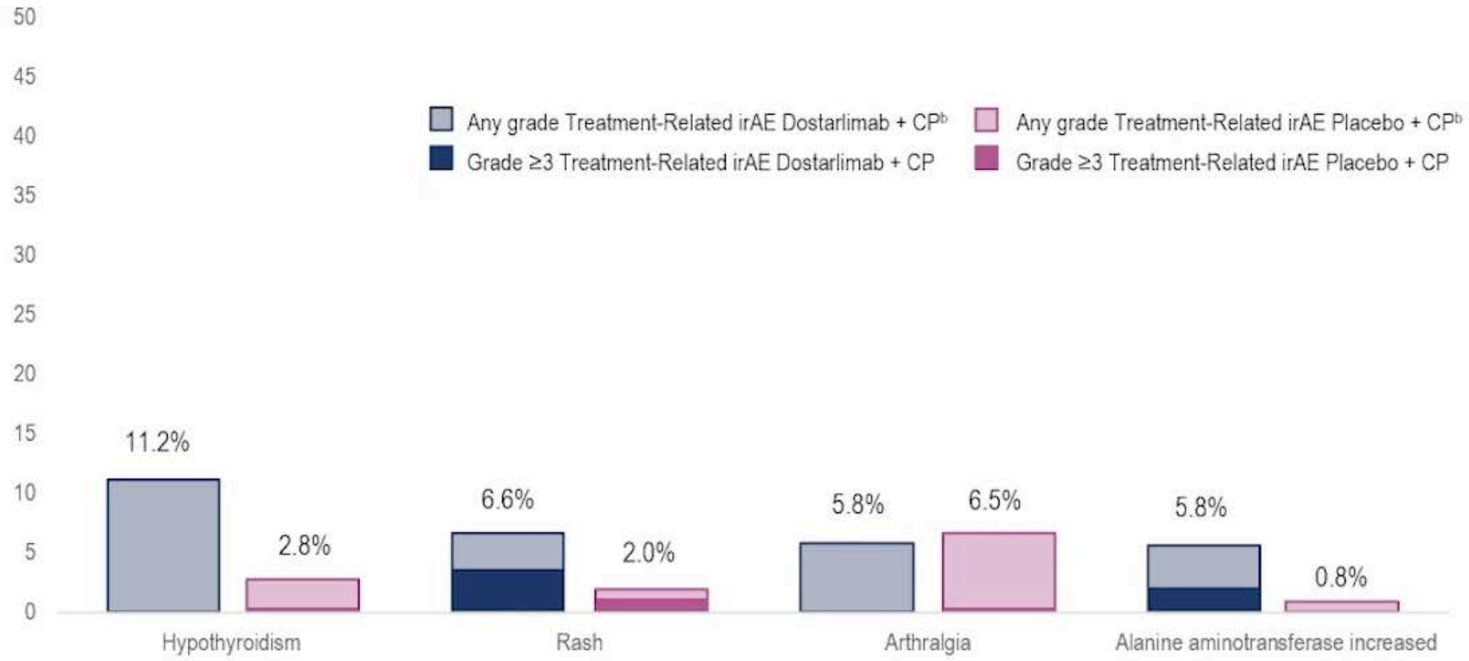
TREATMENT-RELATED irAEs IN ≥5% OF EITHER ARM[a]



[a]All other irAEs that occurred did so at a frequency below 5% in either arm. [b]Immune-related AEs are defined as grade 2 and above from a predefined list. AE, adverse event; ir, immune related.

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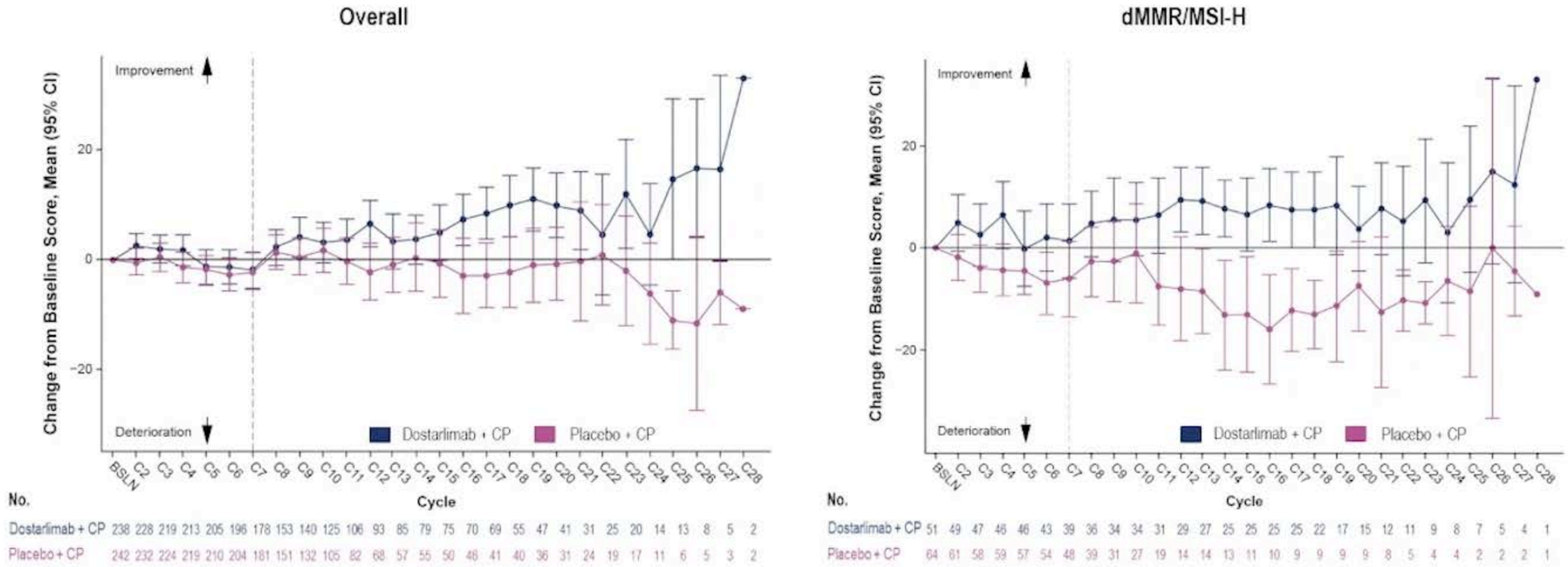
PATIENT-REPORTED OUTCOMES

EORTC QLQ-C30 Global Quality of Life Score



BSLN, baseline; C, cycle; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30.

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CONCLUSIONS

- Dostarlimab + CP demonstrated statistically significant and clinically meaningful PFS benefit with an early OS trend
  - Substantial, unprecedented benefit in dMMR/MSI-H patients
  - Clinically meaningful long-term benefit observed in MMRp/MSS patients
- Safety profile for dostarlimab + CP was manageable and generally consistent with that of the individual drugs
- **Dostarlimab plus carboplatin/paclitaxel represents a new standard of care for patients with primary advanced or recurrent endometrial cancer**

CP, carboplatin/paclitaxel; dMMR, mismatch repair deficient; MMRp, mismatch repair proficient; MSI-H, microsatellite instability-high; MSS, microsatellite stable; OS, overall survival; PFS, progression-free survival.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer

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