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Four-Year Survival Outcomes with Dostarlimab Plus Chemotherapy in dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer in the ENGOT-EN6-NSGO/GOG-3031/RUBY Trial

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I will not be discussing any unlabeled or investigational uses of any pharmaceutical products or medical devices.



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Financial Disclosures

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O Zub has nothing to disclose. **L Gilbert** reports institutional grants from Alkermes, Ascendis Pharma, AstraZeneca, Corcept Therapeutics, Daiichi Sankyo, Espersas, GOG Foundation, GSK, ImmunoGen, IMV Technologies, K-Group Beta/Zentalis Pharmaceuticals, Mersana Therapeutics, MSD, MSK Pharmacologic, Novocure, OncoQuest Pharmaceuticals, Pfizer, Roche, Shattuck Labs, Sutro Biopharma, Tesaro/GSK, and Seagen/Pfizer; consulting fees from MSD, GSK, and Repare Therapeutics; honoraria from GSK; travel support from GOG Foundation, GSK, MSD, and Zentalis Pharmaceuticals; and participation in advisory board meetings for CanariaBio, Corcept Therapeutics, Eisai, GSK, ImmunoGen/AbbVie, Kora Healthcare, and MSD. **A Koliadi** reports consulting fees from Eisai and GSK. **LJ Willmott** reports speakers' bureau fees from AstraZeneca, Eisai, GSK, ImmunoGen/AbbVie, MSD, and Seagen/Pfizer and advisory board fees from AstraZeneca, GSK, ImmunoGen/AbbVie, and Seagen/Pfizer. **D Black** reports institutional grant fees from GSK, fees for being a member of GOG Partners Investigational Council, and medical director/owner of Trials365, LLC. **G Ronzino** has nothing to disclose. **S Sharma** has nothing to disclose. **M Gropp-Meier** reports support for attending meetings and/or travel from GSK. **LM Landrum** reports participation in a scientific advisory board for GSK. **AM Thijs** has nothing to disclose. **E Lokich** has nothing to disclose. **MA Gold** has nothing to disclose. **SE Gill** has nothing to disclose. **C McCourt** has nothing to disclose. **I Cass** has nothing to disclose. **M Grimshaw** and **L Austin** are employed by GSK and hold financial equities in GSK. **MI Edelson** reports advisory board fees from GSK, travel support from Intuitive Surgical, and that spouse was a salaried employee with stock options at MSD (through August 2022) and a current employee at Pfizer. **T Nøttrup** reports consulting/teaching fees from AbbVie, AstraZeneca, BMS, Daiichi Sankyo, GSK, and MSD.

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Background

- For more than a decade, the standard of care for 1L treatment of primary advanced or recurrent EC was chemotherapy; however, long-term outcomes were poor, with a median OS <3 years^{1–5}
- Dostarlimab + CP demonstrated statistically significant and clinically meaningful improvements in PFS and OS vs placebo + CP in primary advanced or recurrent EC, regardless of MMR status^{6,7}
 - Unprecedented survival benefits and improved QoL were seen in the dMMR/MSI-H population^{6–8}
 - Clinically meaningful 7-month OS improvement and maintained QoL were observed in the difficult-to-treat MMRp/MSS population^{7,8}
- Here we present long-term efficacy and safety post hoc results with a minimum of 4 years of follow-up in the **dMMR/MSI-H population** of the phase 3 RUBY trial, as well as complementary conditional survival analysis

1L, first-line; CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; EC, endometrial cancer; MMR, mismatch repair; MMRp, mismatch repair proficient; MSI-H, microsatellite instability-high; MSS, microsatellite stable; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

1. Kalampokas E, et al. *Cancers (Basel)*. 2022;16;14(18):4500. 2. Miller DS, et al. *J Clin Oncol*. 2020;38(33):3841–3850. 3. Sorbe B, et al. *Int J Gynecol Cancer*. 2008;18(4):803–808. 4. de Boer SM, et al. *Lancet Oncol*. 2019;20(9):1273–1285. 5. Salani R, et al. *Am J Obstet Gynecol*. 2011;204(6):466–478. 6. Mirza MR, et al. *N Engl J Med*. 2023;388(23):2145–2158. 7. Powell MA, et al. *Ann Oncol*. 2024;35(8):728–738. 8. Valabrega G, et al. *Int J Gynecol Cancer*. 2025;35(6):101852.



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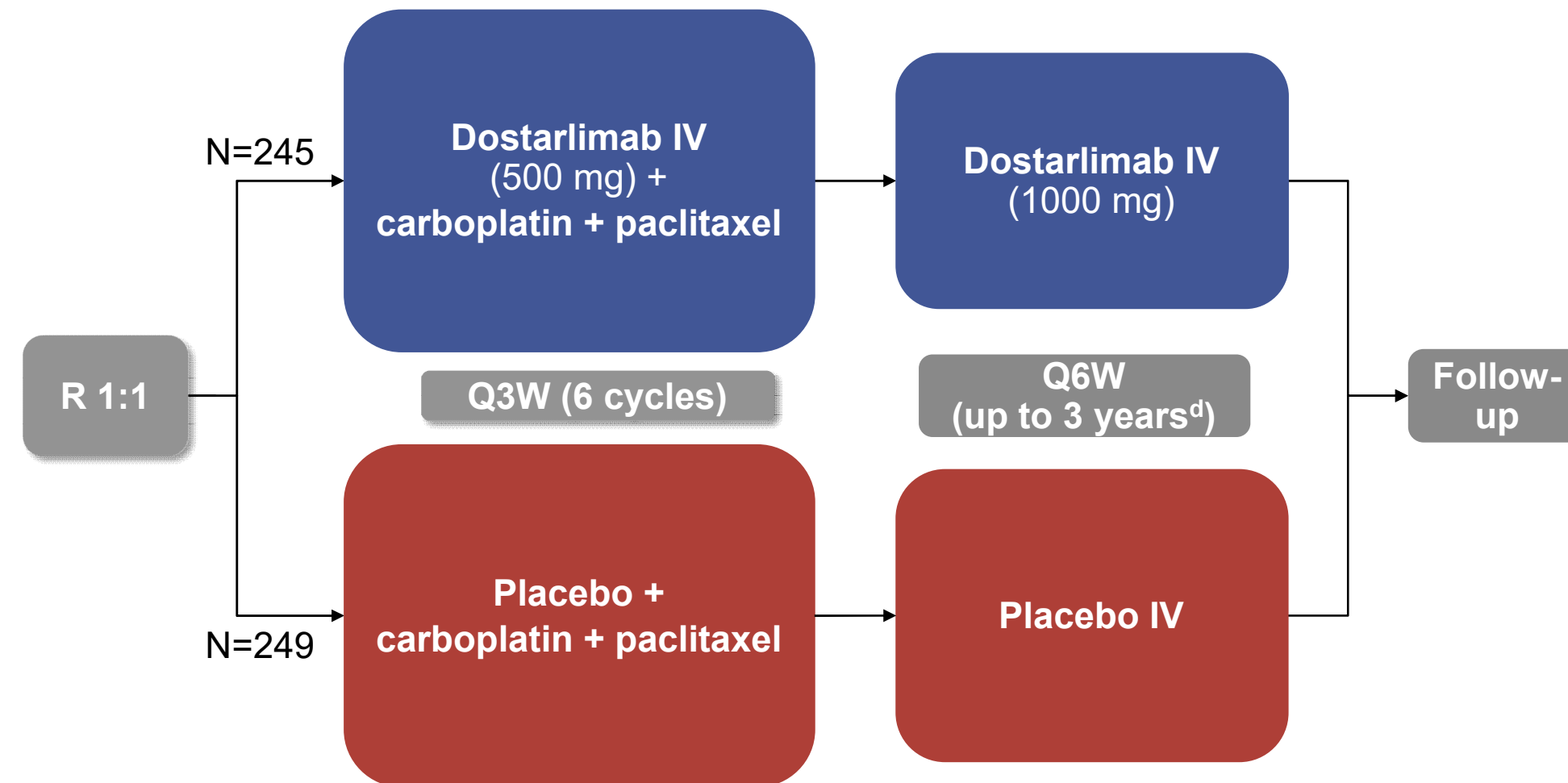
RUBY Part 1 trial design

Eligible patients

- Stage III/IV disease or first recurrent EC^a
 - Carcinosarcoma, clear cell, serous, or mixed histology permitted^b
- Naive to systemic anticancer therapy or had a recurrence or PD ≥6 months after completing systemic anticancer therapy

Stratification

- MMR/MSI status^c
- Prior external pelvic radiotherapy
- Disease status



Primary endpoint

- PFS by INV^e (dMMR/MSI-H and ITT)
- OS (ITT)

Secondary endpoints

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

On-study imaging assessments were performed Q6W (±7 days) from the randomization date until week 25 (cycle 8), followed by Q9W (±7 days) until week 52. Subsequent tumor imaging was performed every 12 weeks (±7 days) until radiographic PD was documented by INV per RECIST v1.1 followed by 1 additional imaging 4–6 weeks later, or subsequent anticancer therapy was started, whichever occurred first. Thereafter, scans may have been performed per standard of care.

^aHistologically/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. ^bMixed histology containing ≥10% carcinosarcoma, clear cell, or serous histology. ^cPatients were randomized based on either local or central MMR/MSI testing results. Central testing was used when 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. ^dTreatment 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. ^eThe threshold for the primary endpoint of PFS was crossed at IA1. Therefore, IA1 was considered the final analysis for PFS.

BICR, blinded independent central review; DCR, disease control rate; dMMR, mismatch repair deficient; DOR, duration of response; EC, endometrial cancer; HRQoL, health-related quality of life; IA1, interim assessment 1; IHC, immunohistochemistry; INV, investigator assessment; ITT, intention-to-treat; IV, intravenous; MMR, mismatch repair; MSI, microsatellite instability; MSI-H, microsatellite instability-high; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PRO, patient-reported outcome; Q3W, every 3 weeks; Q6W, every 6 weeks; Q9W, every 9 weeks; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.



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Demographics and baseline characteristics were similar across arms in the dMMR/MSI-H population

Variable	Dostarlimab + CP (n=53)	Placebo + CP (n=65)
Age, y		
Median (range)	61 (45–81)	66 (39–85)
≥65	23 (43.4)	35 (53.8)
Race		
White	44 (83.0)	56 (86.2)
Not White	9 (17.0)	9 (13.8)
ECOG PS^a		
0	28 (53.8)	39 (60.0)
1	24 (46.2)	26 (40.0)
BMI^a, kg/m²		
Median (range)	30.6 (20.1–54.4)	35.5 (17.9–58.1)

Variable	Dostarlimab + CP (n=53)	Placebo + CP (n=65)
Disease status		
Primary stage III	10 (18.9)	14 (21.5)
Primary stage IV	16 (30.2)	19 (29.2)
Recurrent	27 (50.9)	32 (49.2)
Histology type^b		
Endometrioid	45 (84.9)	54 (83.1)
Non-endometrioid	8 (15.1)	11 (16.9)
Prior external pelvic radiotherapy		
Yes	8 (15.1)	13 (20.0)
No	45 (84.9)	52 (80.0)

Values shown are n (%) unless noted otherwise.

^aNumber of patients with ECOG PS score and BMI data: 52 dostarlimab + CP dMMR/MSI-H, 65 placebo + CP dMMR/MSI-H.

^bData included most recent histology type.

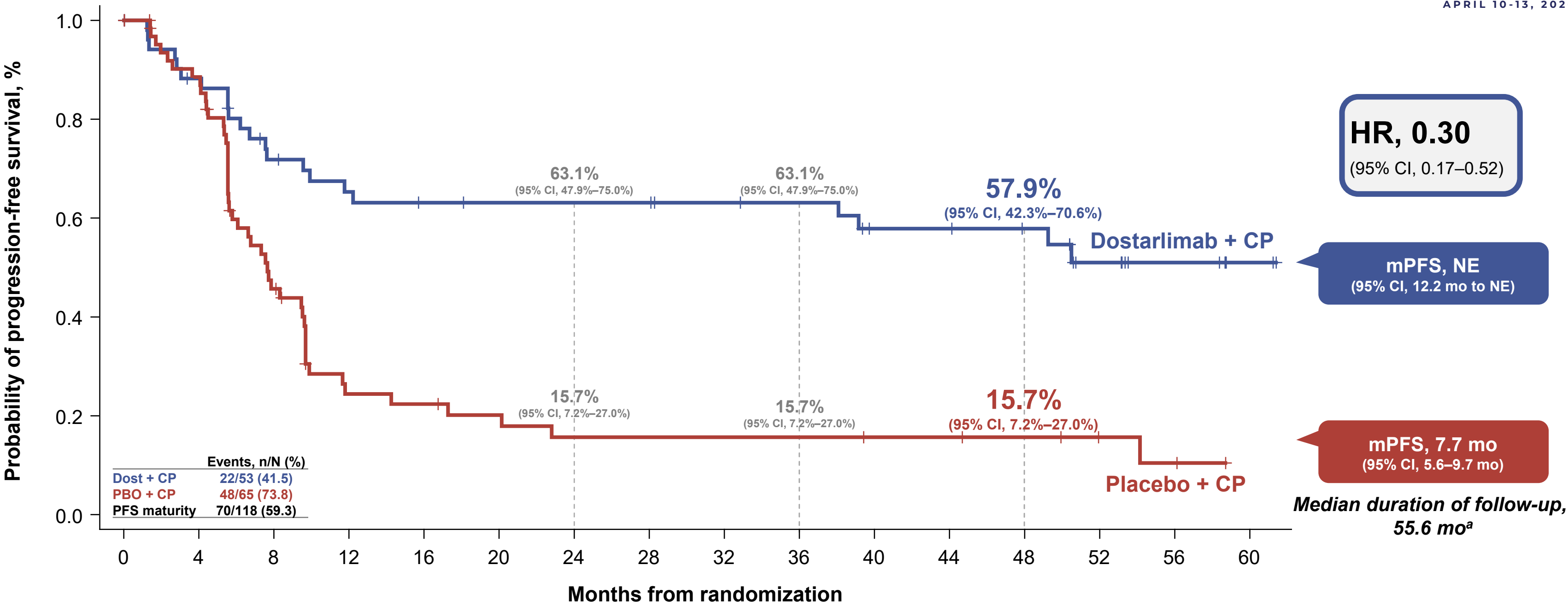
BMI, body mass index; CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; MSI-H, microsatellite instability-high.



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PFS benefit sustained at 4 years with dostarlimab + CP

Only 4 new progression events with an additional 2.5 years of follow-up, with median PFS not reached



^aMedian expected follow-up, 55.6 months (range, 49.9–67.7 months).
CP, carboplatin-paclitaxel; dost, dostarlimab; m, median; NE, not estimable; PBO, placebo; PFS, progression-free survival.

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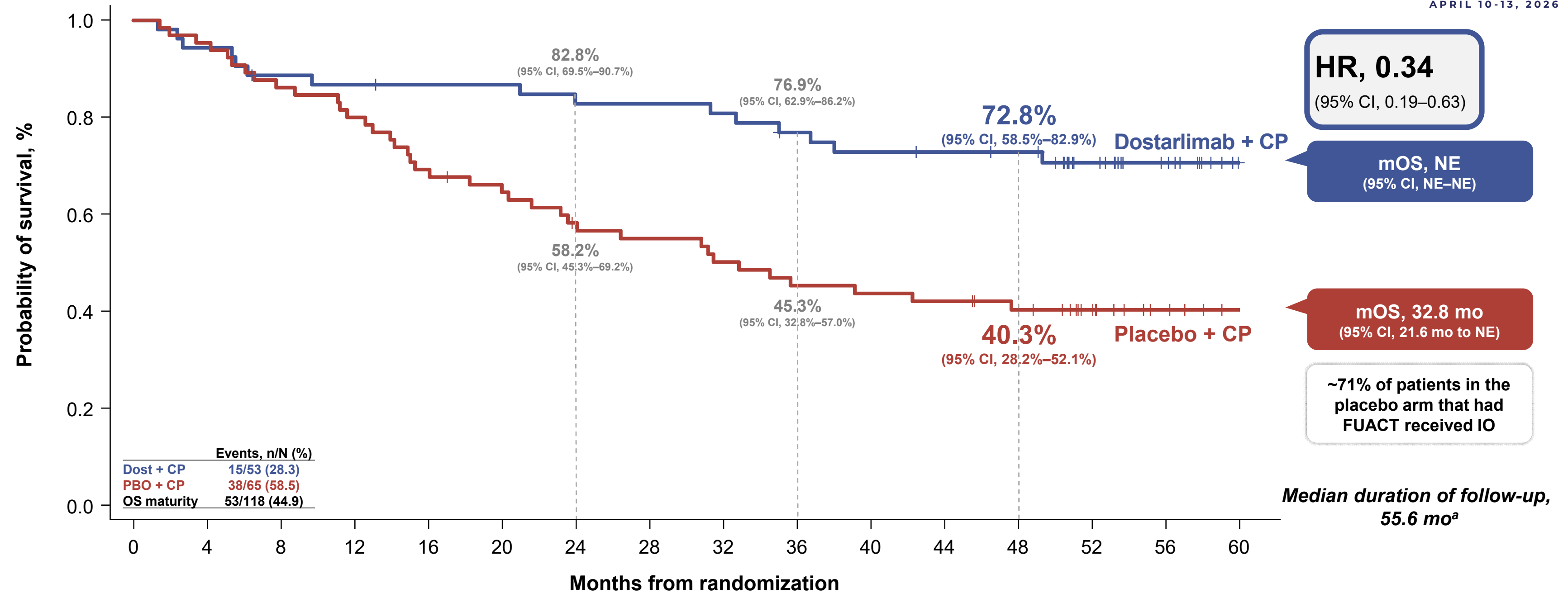
Robust OS benefit maintained at 4 years with dostarlimab + CP

Median OS not reached, with a 66% reduction in risk of death vs placebo + CP in the dMMR/MSI-H population



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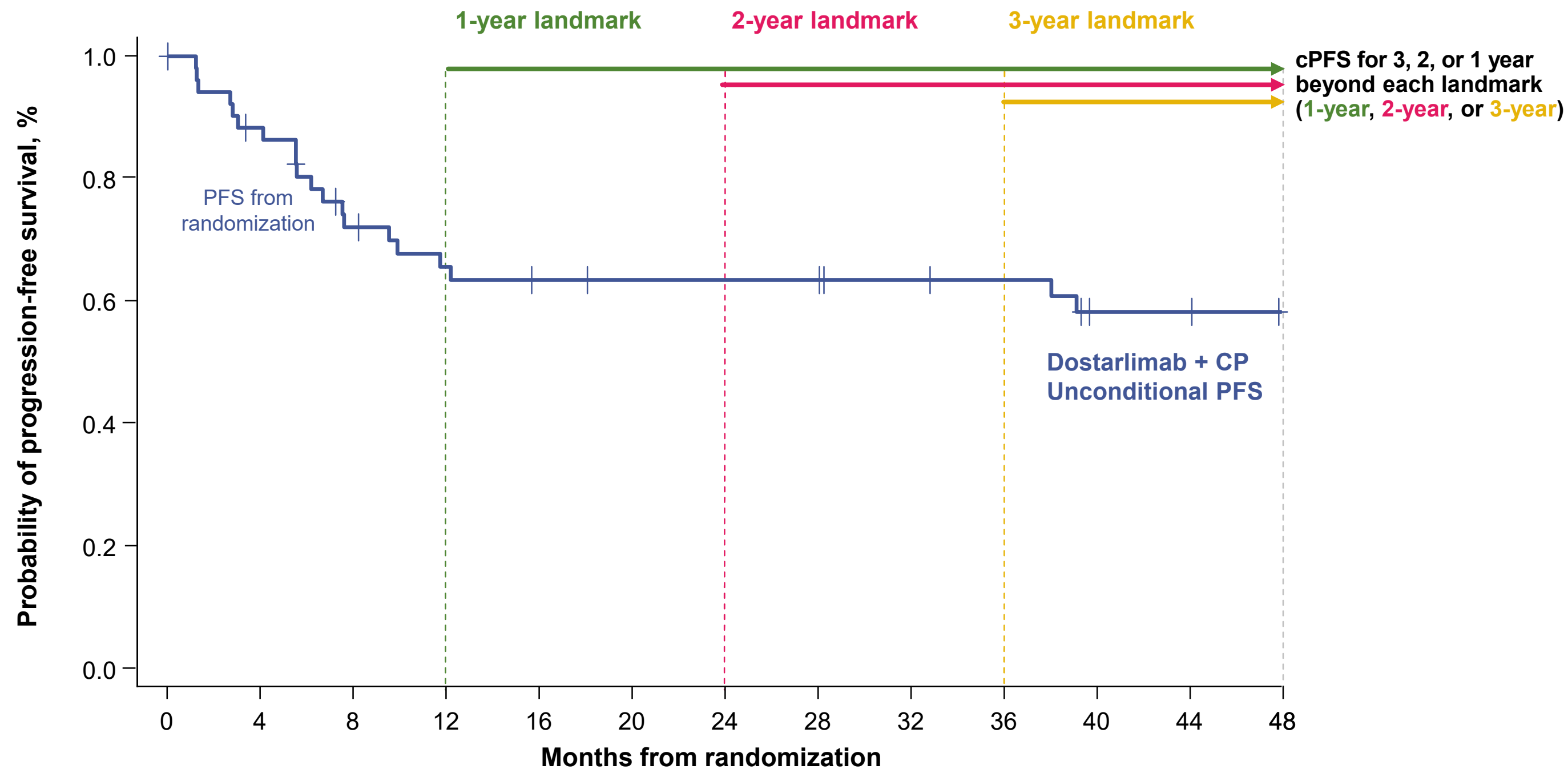
^aMedian expected follow-up, 55.6 months (range, 49.9–67.7 months).

CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; dost, dostarlimab; FUACT, follow-up anticancer treatment; IO, immunotherapy; m, median; MSI-H, microsatellite instability-high; NE, not estimable; PBO, placebo; OS, overall survival.



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Conditional PFS: evaluates the probability of being progression free and alive at time points beyond a prespecified landmark and may help guide patient counseling

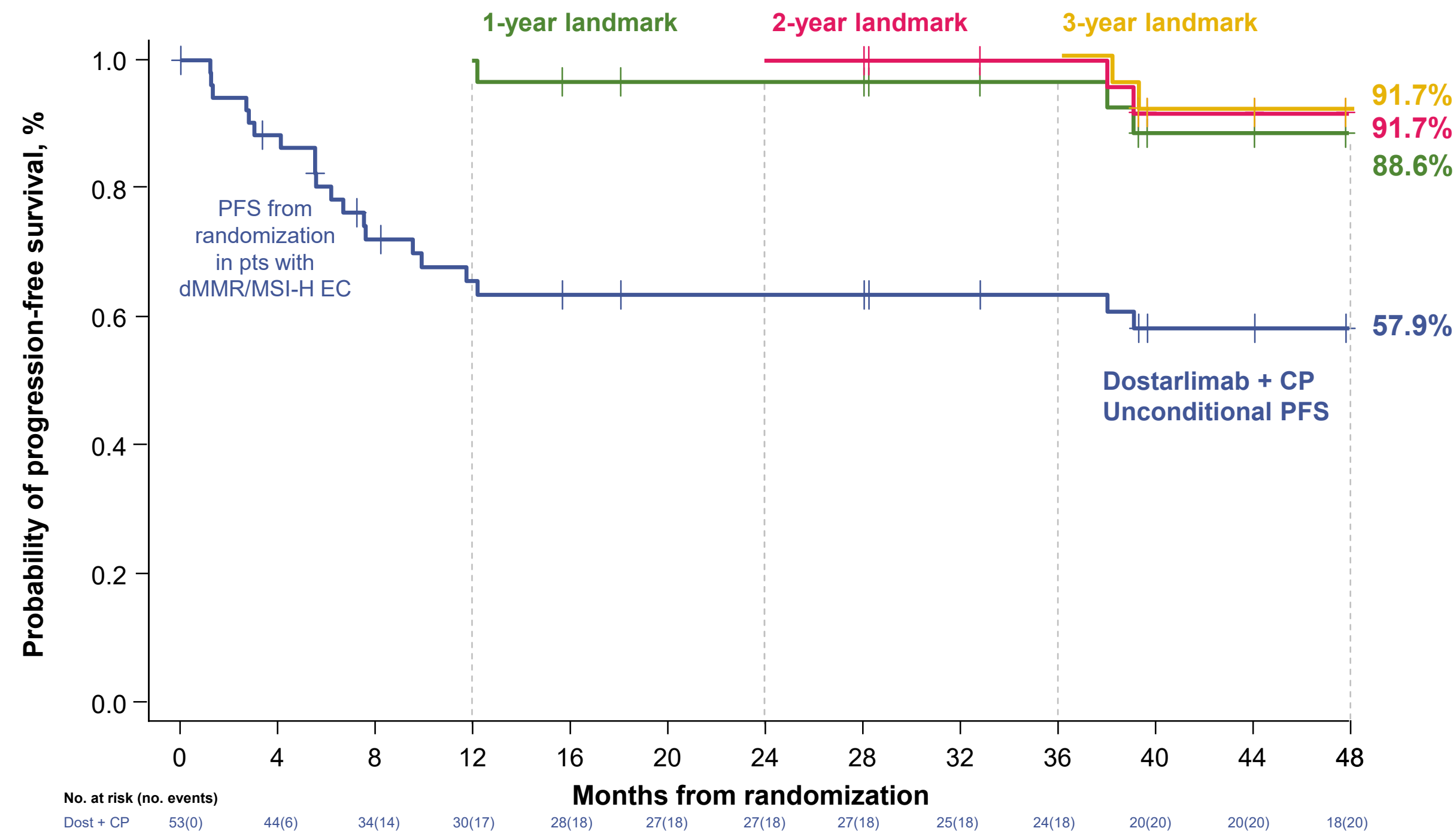


Post hoc analysis.
CP, carboplatin-paclitaxel; cOS, conditional overall survival; cPFS, conditional progression-free survival.



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Conditional PFS: pts progression free at 2 years had >90% probability of remaining progression free and alive at 4 years



dMMR/MSI-H population	Dostarlimab + CP
3-year progression-free probability from 1-year landmark	88.6% (95% CI, 68.5%–96.2%)
2-year progression-free probability from 2-year landmark	91.7% (95% CI, 70.6%–97.8%)
1-year progression-free probability from 3-year landmark	91.7% (95% CI, 70.6%–97.8%)

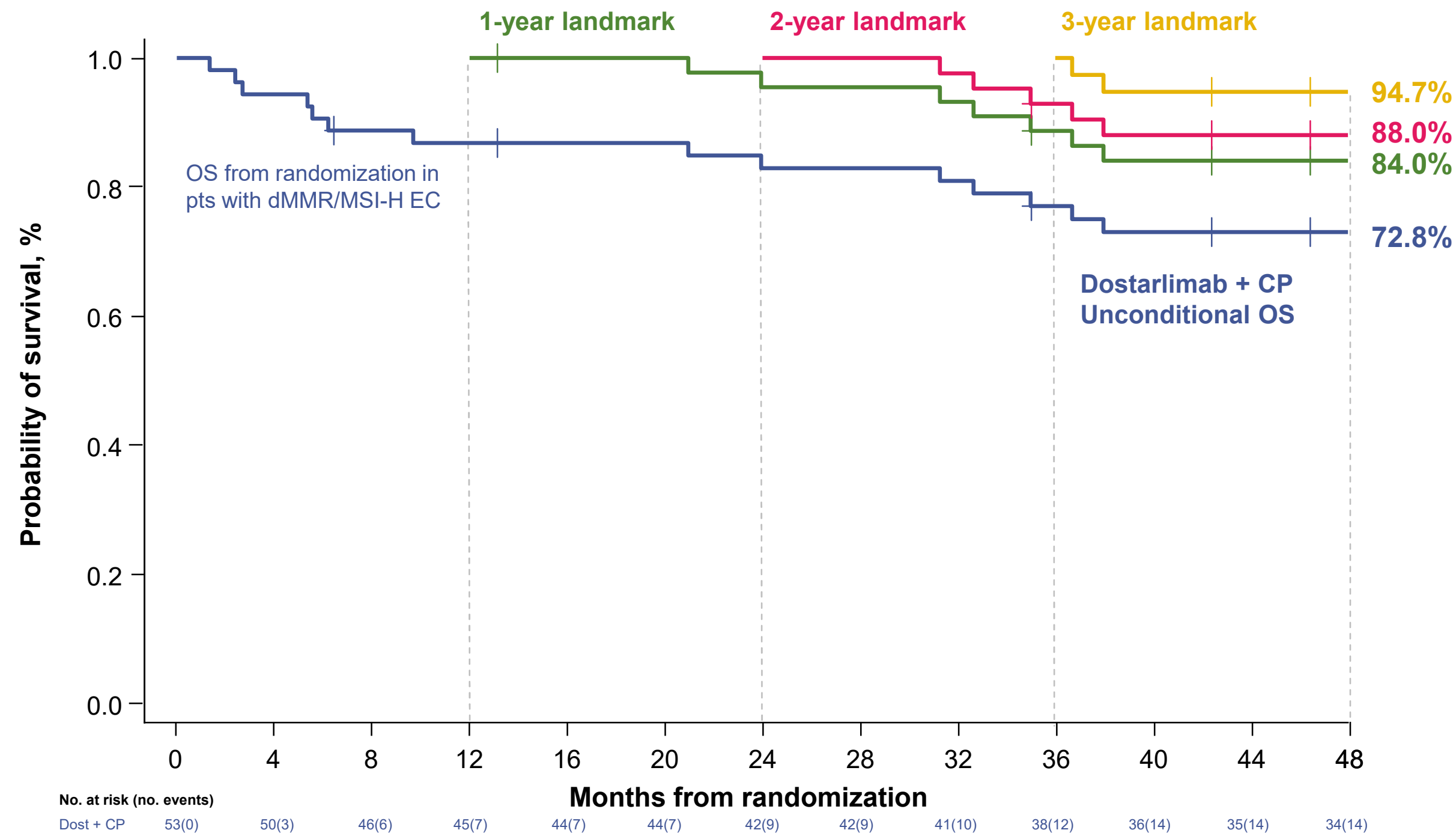
Conditional PFS evaluates the probability of remaining progression free and alive for additional time from a specified time point (eg, 1-year, 2-year, and 3-year landmark).

Post hoc analysis. Median expected follow-up, 55.6 months (range, 49.9–67.7 months).
CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; dost, dostarlimab; MSI-H, microsatellite instability-high; PFS, progression-free survival.



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Conditional OS: pts alive at 1 and 2 years had >80% probability of remaining alive at 4 years



Post hoc analysis. Median expected follow-up, 55.6 months (range, 49.9–67.7 months).
CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; dost, dostarlimab; MSI-H, microsatellite instability-high; OS, overall survival.

dMMR/MSI-H population	Dostarlimab + CP
3-year survival probability from 1-year landmark	84.0% (95% CI, 69.3%–92.0%)
2-year survival probability from 2-year landmark	88.0% (95% CI, 73.5%–94.8%)
1-year survival probability from 3-year landmark	94.7% (95% CI, 80.6%–98.7%)

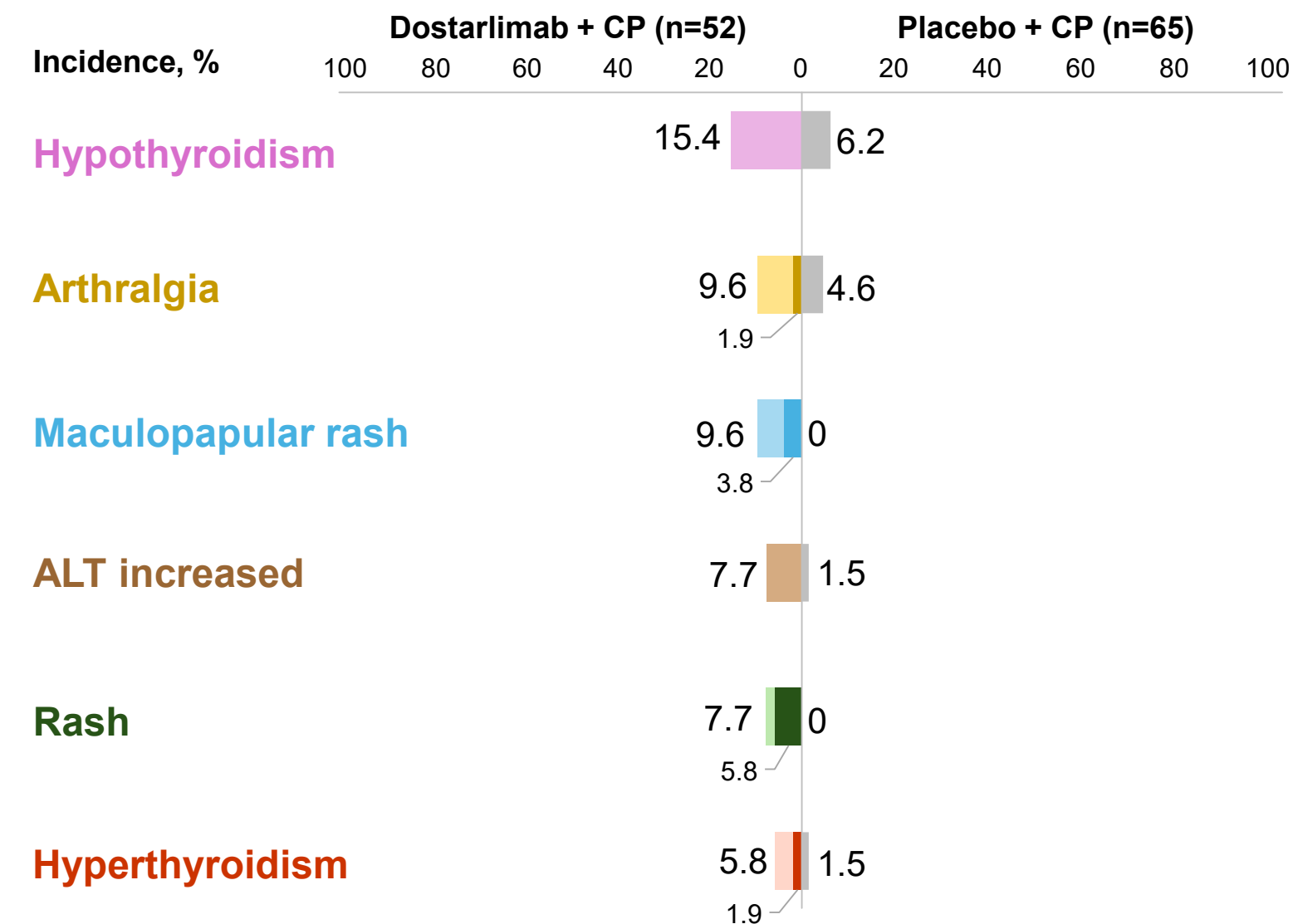
Conditional OS evaluates the probability of being alive for additional time from a specified time point (eg, 1-year, 2-year, 3-year landmark).



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Dostarlimab-related irAEs remained low throughout the study

6 most common dostarlimab-related irAEs^{a,b} (total incidence, %)



Darker shades indicate grade ≥ 3 dostarlimab-/placebo-related irAEs

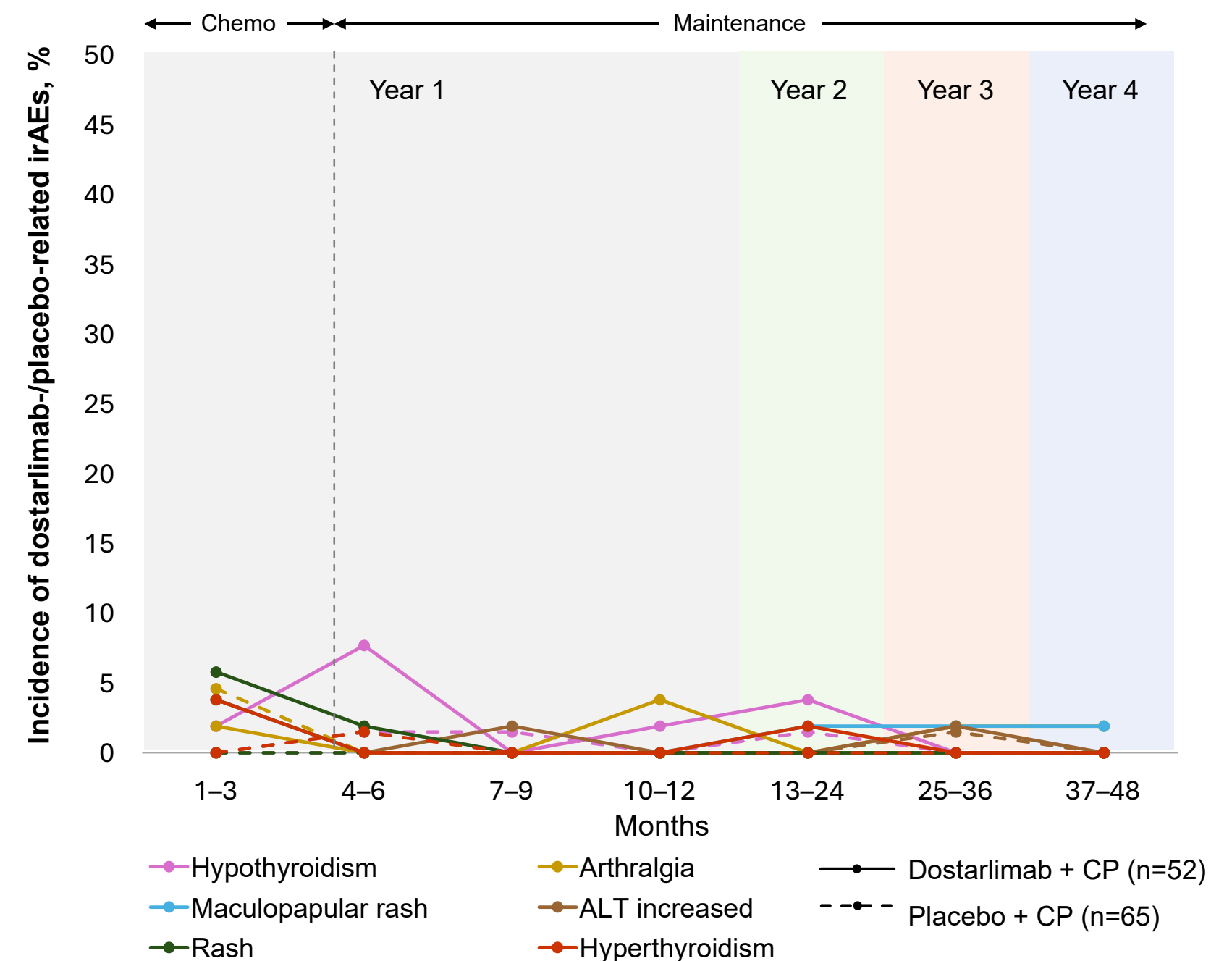
^aDostarlimab-/placebo-related irAEs in $\geq 5\%$ of the dostarlimab arm.

^birAEs were classified as CTCAE grade ≥ 2 from a predefined list of preferred terms.

^cIncidence per time period calculated as total incidence per total patient number in the trial arm.

ALT, alanine aminotransferase; Chemo, chemotherapy; CP, carboplatin-paclitaxel; CTCAE, Common Terminology Criteria for Adverse Events; dMMR, mismatch repair deficient; irAE, immune-related adverse event; MSI-H, microsatellite instability-high.

6 most common dostarlimab-related irAEs^a (years 1–4^c, %)



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Conclusions

- Dostarlimab + CP showed sustained long-term PFS and OS benefits in patients with dMMR/MSI-H primary advanced or recurrent EC, with median PFS and OS not reached at over 4 years of follow-up
 - Plateauing of PFS curve with only 4 progression events with additional 2.5 years of follow-up demonstrating durable disease control
 - 4-year overall survival rate was 72.8%
- Conditional survival estimates improve with every year that patients remain alive, providing clinicians with a valuable tool for counseling patients on their probability of long-term survival
- There were no new safety signals, and dostarlimab-related irAE incidences remained low with additional follow-up

At 4 years, RUBY demonstrated sustained remission and long-term survival benefit, suggesting the potential for curative intent with dostarlimab + CP in patients with primary advanced or recurrent dMMR/MSI-H EC

CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; EC, endometrial cancer; MSI-H, microsatellite instability-high; OS, overall survival; PFS, progression-free survival; TRAE, treatment-related adverse event.



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Acknowledgments

We sincerely thank the patients and their families for participating in this trial, and all the investigators and cooperative groups.



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Appendix



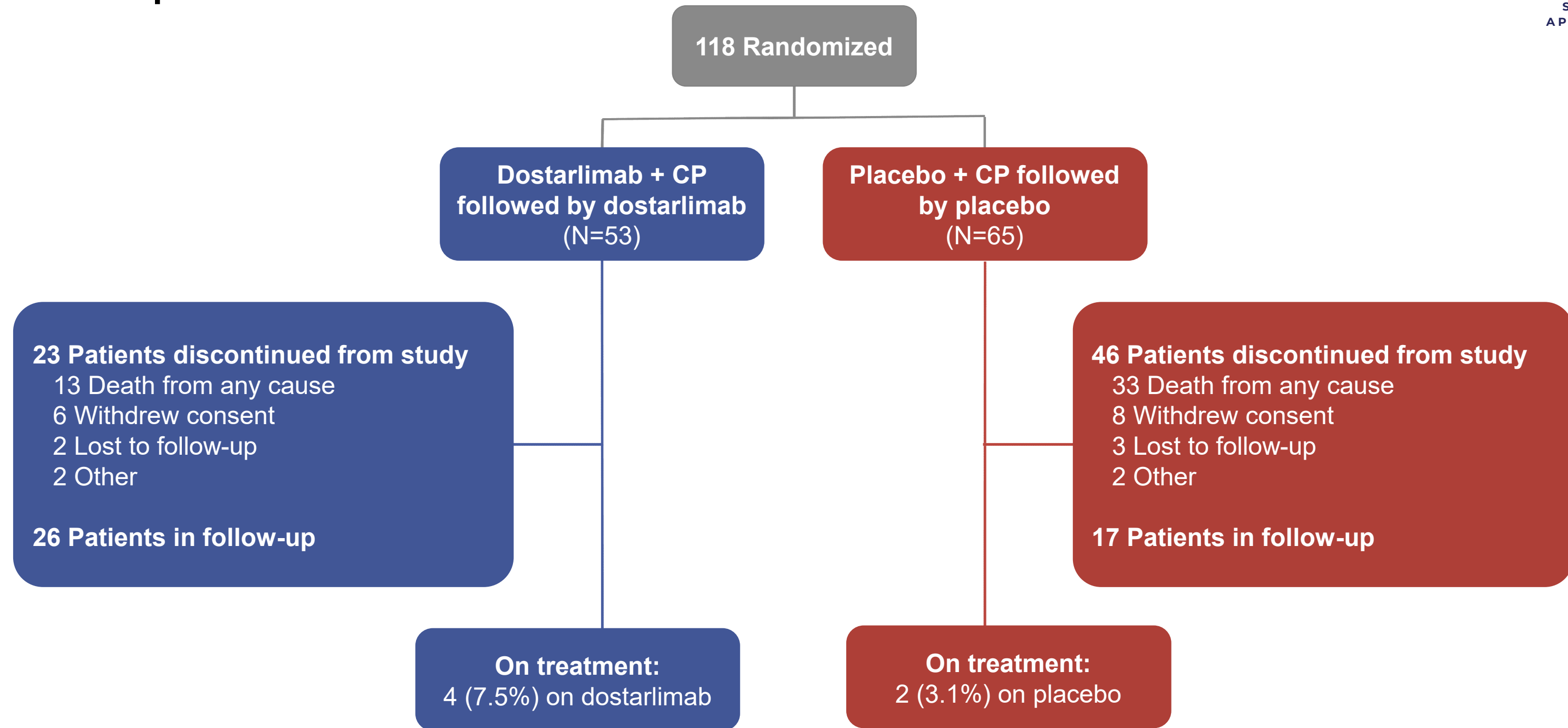
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Patient disposition in dMMR/MSI-H population with >4 years of follow-up



Data cutoff date: April 22, 2025.

Median expected follow-up 55.6 months (range 49.9-67.7). Duration of follow-up is defined as the time from randomization to cut off date

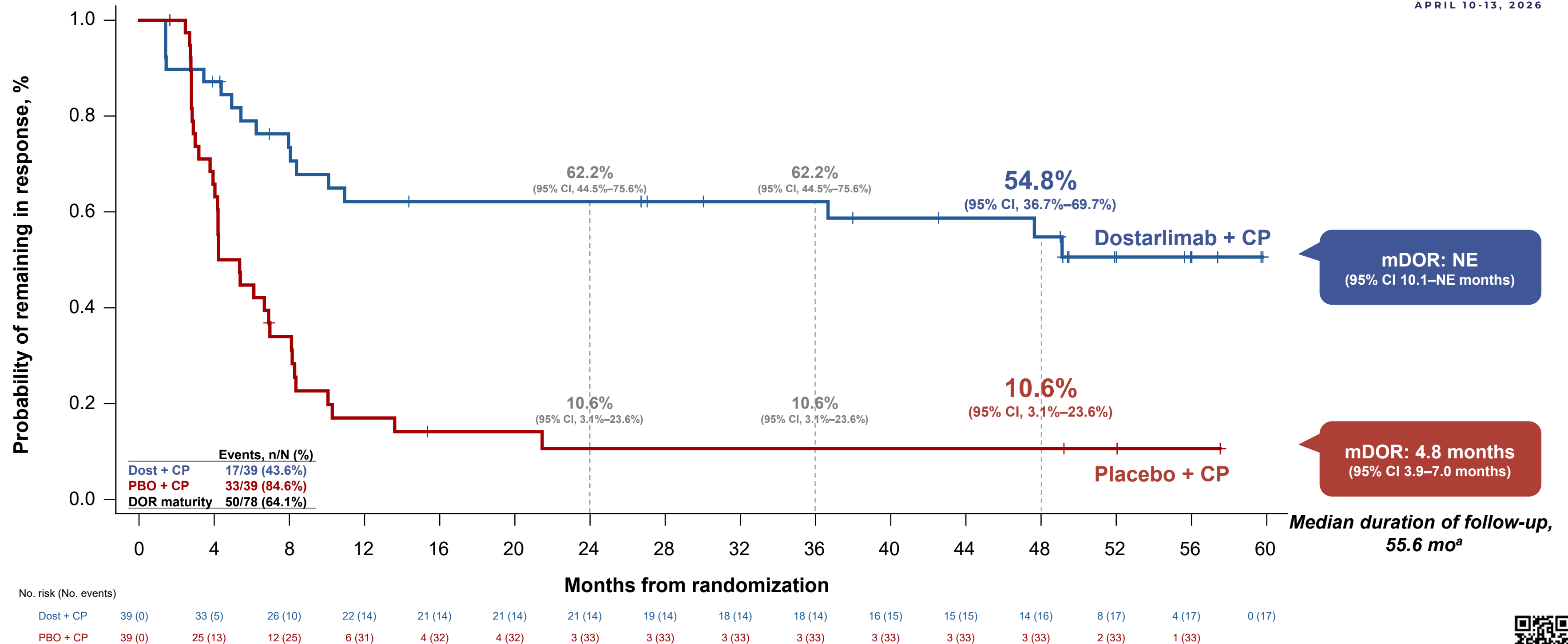
CP, carboplatin-paclitaxel.



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DOR benefit was maintained at 4 years with dostarlimab + CP

Improvement in DOR of greater than 50% was seen at 3 years and greater than 40% at 4 years in the dMMR/MSI-H population



^aMedian expected follow-up, 55.6 months (range, 49.9–67.7 months).

CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; DOR, duration of response; Dost, dostarlimab; MSI-H, microsatellite instability-high; NE, not estimable; PBO, placebo.



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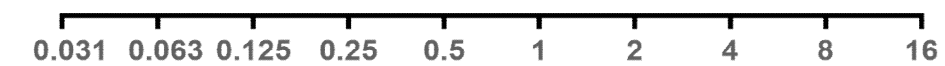
Consistent OS benefit was observed across most exploratory subgroups with dostarlimab + CP in the dMMR/MSI-H population

Categories		Dostarlimab + CP N=53 (No. of events/No. of patients)	Placebo + CP N=65 (No. of events/No. of patients)	Dostarlimab + CP (mOS, months)	Placebo + CP (mOS, months)	Favors dostarlimab + CP	Favors placebo + CP	HR (95% CI)
All patients		15/53	38/65	NE	32.8	—●—		0.34 (0.185–0.626)
Age	<65 years	7/30	15/30	NE	NE	—●—		0.39 (0.157–0.950)
	≥65 years	8/23	23/35	NE	32.1	—●—		0.41 (0.180–0.910)
Race	White	12/44	31/56	NE	35.6	—●—		0.40 (0.206–0.784)
	Other	3/9	7/9	NE	24.0	—●—		0.28 (0.069–1.175)
Region	North America	11/36	30/50	NE	31.1	—●—		0.39 (0.194–0.779)
	Europe	4/17	8/15	NE	47.6	—●—		0.40 (0.121–1.339)
	Eastern Europe	2/7	5/7	NE	21.6	—●—		0.44 (0.084–2.268)
	Western Europe	2/10	3/8	NE	NE	—●—		0.48 (0.079–2.879)
Histology category	Endometrioid carcinoma	12/45	32/54	NE	32.8	—●—		0.34 (0.177–0.670)
	Other	3/8	6/11	NE	30.8	—●—		0.78 (0.194–3.152)
Prior external pelvic RT	Yes	0/8	11/13	NE	23.6			NA
	No	15/45	27/52	NE	35.6	—●—		0.56 (0.299–1.061)
Disease status	Recurrent	4/27	23/32	NE	24.0	—●—		0.12 (0.043–0.361)
	Primary stage III	4/9	3/14	NE	NE		—●—	2.66 (0.593–11.914)
	Primary Stage IV	7/17	12/19	NE	18.2	—●—		0.54 (0.213–1.385)
No disease at baseline		0/4	1/8	NE	NE			NA

Median expected follow-up, 55.6 months (range, 49.9–67.7 months).

CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; MSI-H, microsatellite instability-high; NA, not available;

NE, not estimable; OS, overall survival.



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With less progression events, fewer patients in the dostarlimab + CP arm received FUACT in the dMMR/MSI-H population

Among those who received FUACT, irrespective of progression, the most common FUACT received was immunotherapy

Variable, n (%)	Dostar + CP (N=53)	Placebo + CP (N=65)
Any FUACT^a	17 (32.1%)	41 (63.1%)
Immunotherapy	9/17 (52.9%)	29/41 (70.7%)
Pembrolizumab	4/17 (23.5%)	21/41 (51.2%)
Pembrolizumab/Lenvatinib	3/17 (17.6%)	4/41 (9.8%)
Dostarlimab	1/17 (5.9%)	4/41 (9.8%)
Other	2/17 (11.8%)	1/41 (2.4%)
Chemotherapy	7/17 (41.2%)	12/41 (29.3%)
Hormonal Therapy	4/17 (23.5%)	12/41 (29.3%)
Radiation Therapy	3/17 (17.6%)	8/41 (19.5%)
Other	2/17 (11.8%)	0

^aAll patients in the trial who received follow-up anticancer therapy, irrespective of progression.
CP, carboplatin-paclitaxel; FUACT, follow-up anticancer therapy.



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Safety profile in the dMMR/MSI-H population with no new safety signals

Parameter, n (%)	Dostar + CP (N=52)	PBO + CP (N=65)
Any Adverse Events	52 (100)	65 (100)
Any Treatment-Related AEs	52 (100)	65 (100)
Any Grade 3 or Greater AEs	40 (76.9)	43 (66.2)
Any Grade ≥3 Treatment-Related AEs	32 (61.5)	32 (49.2)
Any Serious AEs	18 (34.6)	22 (33.8)
Any Treatment-Related Serious AEs	11 (21.2)	9 (13.8)
Any AE Leading to Treatment Discontinuation	11 (21.2)	14 (21.5)
Any AE with Outcome of Death	2 (3.8)	0
Any Treatment-Related AE Leading to Death	2 (3.8)	0
Related to Dostarlimab/Placebo	2 (3.8)	0
Related to Dostarlimab/Placebo Only	1 (1.9)	0
Any Immune-Related AE	39 (75.0)	27 (41.5)
Related to Dostarlimab/Placebo ^a	29 (55.8)	11 (16.9)
Any Infusion-Related Reactions	12 (23.1)	13 (20.0)

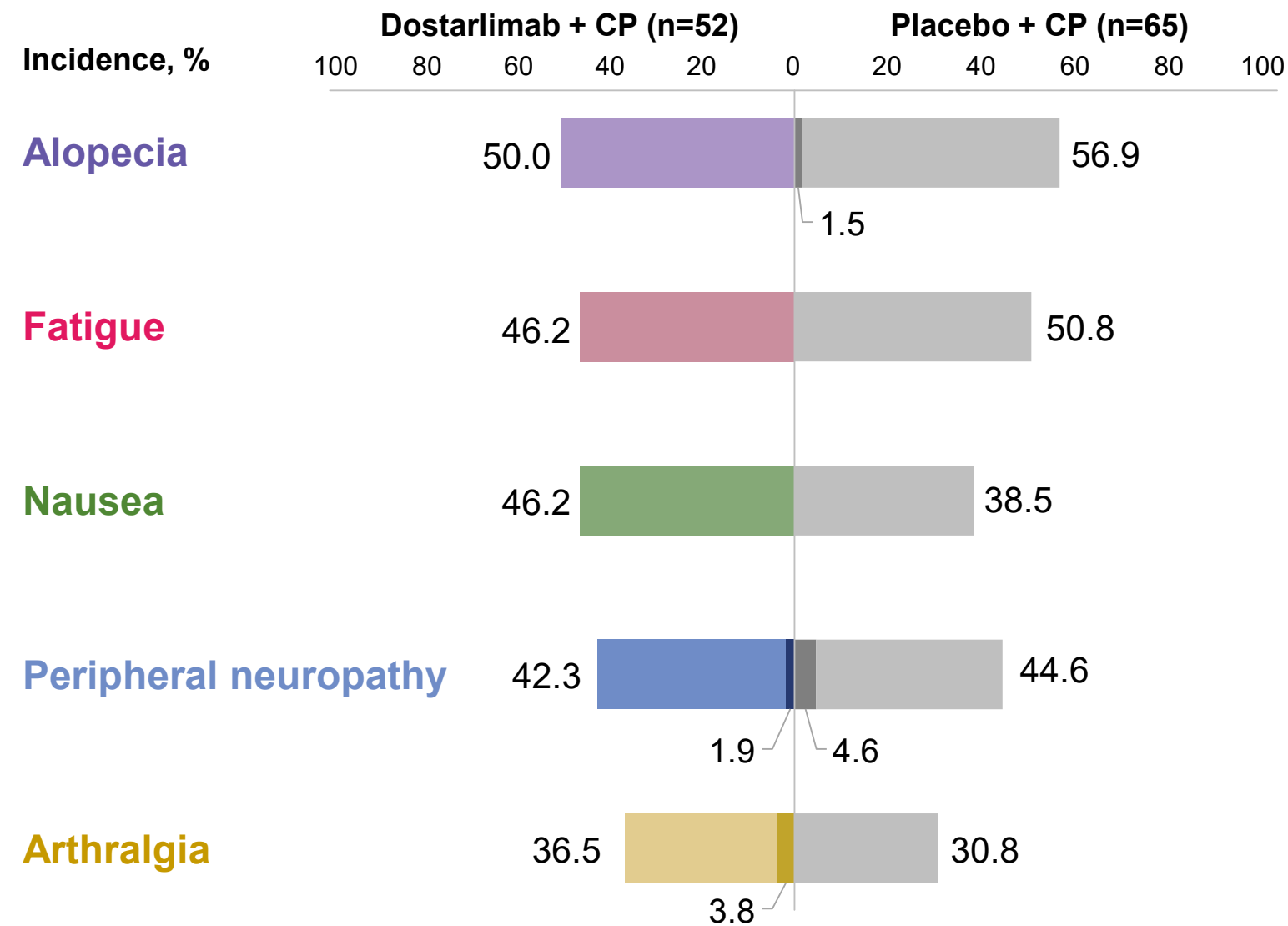
^aAEs related to dostarlimab or placebo and may also have been related to carboplatin and/or paclitaxel.
AE, adverse event; CP, carboplatin-paclitaxel; dostar, dostarlimab; PBO, placebo.



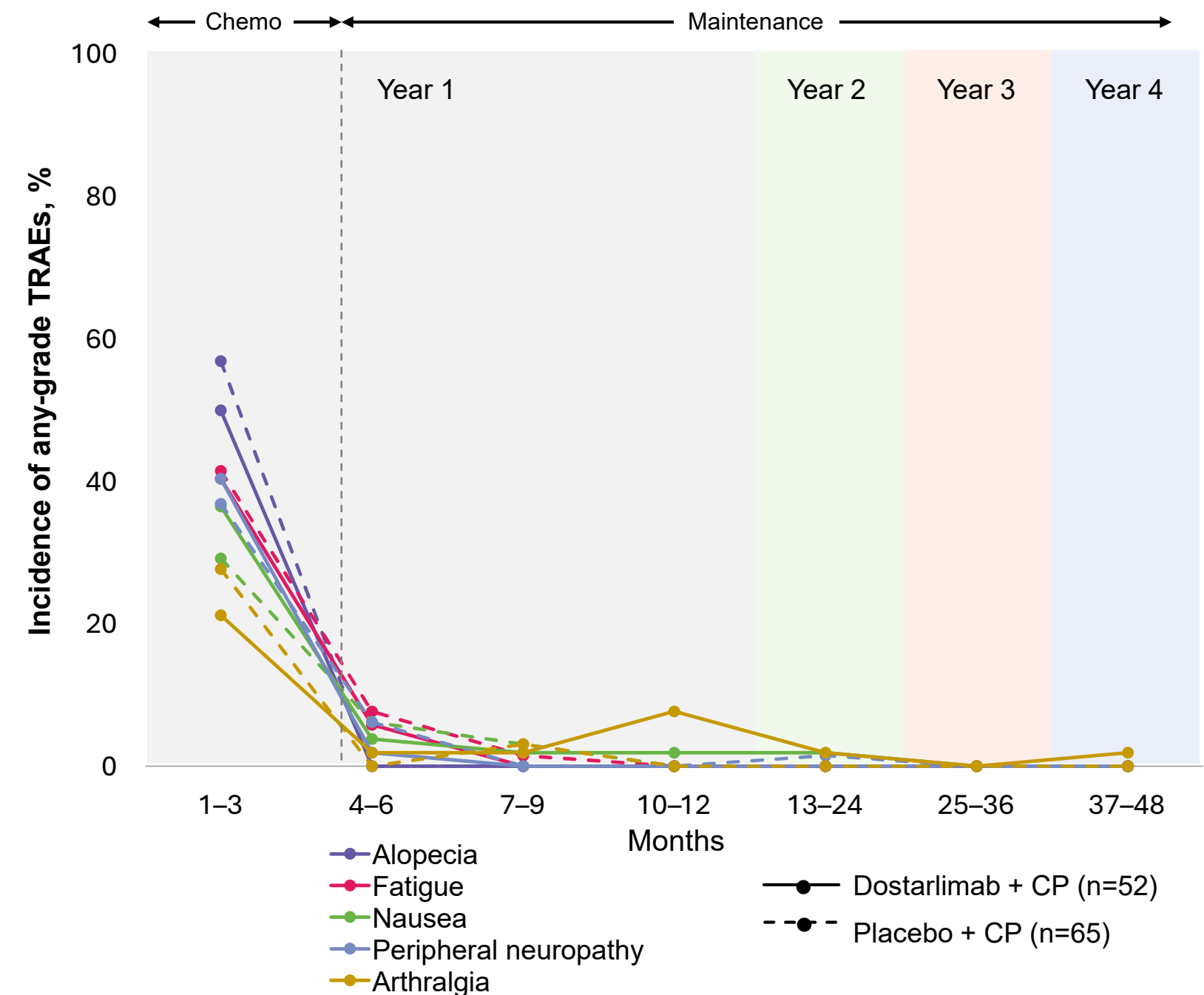
Scan for slides and
supplemental data

No new safety signals were observed with long-term follow-up in the dMMR/MSI-H population

5 most common any-grade TRAEs^a (total incidence, %)



5 most common any-grade TRAEs^a (years 1–4^b, %)



^a5 most common any-grade TRAEs in the dostarlimab arm.

^bIncidence per time period calculated as total incidence per total patient number in the trial arm.

Chemo, chemotherapy; CP, carboplatin-paclitaxel; dMMR, mismatch repair deficient; MSI-H, microsatellite instability-high; TRAE, treatment-related adverse event.



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