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Efficacy and Safety of Cadonilimab Combined with Chemotherapy as the First-line Treatment for Advanced/Recurrent Endometrial Cancer (CARE Trial): A Multi-center, Single-arm, Phase II Trial

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Financial Disclosure

[Yang Sun]

I have no financial disclosures and will not be discussing any unlabeled or investigational uses of any pharmaceutical products or medical devices.

Background

- **Anti-PD-1/PD-L1 antibody combined with chemotherapy is the standard first-line treatment for patients with advanced/recurrent cancer.**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer

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ABSTRACT

BACKGROUND
Standard first-line chemotherapy for endometrial cancer is paclitaxel plus carboplatin. The benefit of adding pembrolizumab to chemotherapy remains unclear.

METHODS
In this double-blind, placebo-controlled, randomized, phase 3 trial, we assigned 816 patients with measurable disease (stage III or IVA) or stage IVB or recurrent endometrial cancer in a 1:1 ratio to receive pembrolizumab or placebo along with combination therapy with paclitaxel plus carboplatin. The administration of pembrolizumab or placebo was planned in 6 cycles every 3 weeks, followed by up to 14 maintenance cycles every 6 weeks. The patients were stratified into two cohorts according to whether they had mismatch repair–deficient (dMMR) or mismatch repair–proficient (pMMR) disease. Previous adjuvant chemotherapy was permitted if the treatment-free interval was at least 12 months. The primary outcome was progression-free survival in the two cohorts. Interim analyses were scheduled to be triggered after the occurrence of at least 84 events of death or progression in the dMMR cohort and at least 196 events in the pMMR cohort.

RESULTS
In the 12-month analysis, Kaplan–Meier estimates of progression-free survival in the dMMR cohort were 74% in the pembrolizumab group and 38% in the placebo group (hazard ratio for progression or death, 0.30; 95% confidence interval [CI], 0.19 to 0.48; P<0.001), a 70% difference in relative risk. In the pMMR cohort, median progression-free survival was 13.1 months with pembrolizumab and 8.7 months with placebo (hazard ratio, 0.54; 95% CI, 0.41 to 0.71; P<0.001). Adverse events were as expected for pembrolizumab and combination chemotherapy.

CONCLUSIONS
In patients with advanced or recurrent endometrial cancer, the addition of pembrolizumab to standard chemotherapy resulted in significantly longer progression-free survival than with chemotherapy alone. (Funded by the National Cancer Institute and others; NRG-GY018 ClinicalTrials.gov number, NCT03914612.)

The authors' affiliations are listed in the Appendix. Dr. Eskander can be contacted at reskander@health.ucsd.edu or at the University of California, San Diego, Rebecca and John Moores Comprehensive Cancer Center, 3855 Health Sciences Dr., La Jolla, CA 92093.

Drs. Powell and Aghajanian contributed equally to this article.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer

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ABSTRACT

BACKGROUND
Dostarlimab is an immune-checkpoint inhibitor that targets the programmed cell death 1 receptor. The combination of chemotherapy and immunotherapy may have synergistic effects in the treatment of endometrial cancer.

METHODS
We conducted a phase 3, global, double-blind, randomized, placebo-controlled trial. Eligible patients with primary advanced stage III or IV or first recurrent endometrial cancer were randomly assigned in a 1:1 ratio to receive either dostarlimab (500 mg) or placebo, plus carboplatin (area under the concentration–time curve, 5 mg per milliliter per minute) and paclitaxel (175 mg per square meter of body-surface area), every 3 weeks (six cycles), followed by dostarlimab (1000 mg) or placebo every 6 weeks for up to 3 years. The primary end points were progression-free survival as assessed by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, and overall survival. Safety was also assessed.

RESULTS
Of the 494 patients who underwent randomization, 118 (23.9%) had mismatch repair–deficient (dMMR), microsatellite instability–high (MSI-H) tumors. In the dMMR–MSI-H population, estimated progression-free survival at 24 months was 61.4% (95% confidence interval [CI], 46.3 to 73.4) in the dostarlimab group and 15.7% (95% CI, 7.2 to 27.0) in the placebo group (hazard ratio for progression or death, 0.28; 95% CI, 0.16 to 0.50; P<0.001). In the overall population, progression-free survival at 24 months was 36.1% (95% CI, 29.3 to 42.9) in the dostarlimab group and 18.1% (95% CI, 13.0 to 23.9) in the placebo group (hazard ratio, 0.64; 95% CI, 0.51 to 0.80; P<0.001). Overall survival at 24 months was 71.3% (95% CI, 64.5 to 77.1) with dostarlimab and 56.0% (95% CI, 48.9 to 62.5) with placebo (hazard ratio for death, 0.64; 95% CI, 0.46 to 0.87). The most common adverse events that occurred or worsened during treatment were nausea (53.9% of the patients in the dostarlimab group and 45.9% of those in the placebo group), alopecia (53.5% and 50.0%), and fatigue (51.9% and 54.5%). Severe and serious adverse events were more frequent in the dostarlimab group than in the placebo group.

CONCLUSIONS
Dostarlimab plus carboplatin–paclitaxel significantly increased progression-free survival among patients with primary advanced or recurrent endometrial cancer, with a substantial benefit in the dMMR–MSI-H population. (Funded by GSK; RUBY ClinicalTrials.gov number, NCT03981796.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Mirza can be contacted at mansoor@rh.regionh.dk or at the Department of Oncology, Rigshospitalet, Copenhagen University Hospital, Department of Cancer Treatment–5073, Blegdamsvej 9, 2100 Copenhagen, Denmark.

*A list of the RUBY investigators is provided in the Supplementary Appendix, available at NEJM.org.

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Durvalumab Plus Carboplatin/Paclitaxel Followed by Maintenance Durvalumab With or Without Olaparib as First-Line Treatment for Advanced Endometrial Cancer: The Phase III DUO-E Trial

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ABSTRACT

PURPOSE Immunotherapy and chemotherapy combinations have shown activity in endometrial cancer, with greater benefit in mismatch repair (MMR)–deficient (dMMR) than MMR-proficient (pMMR) disease. Adding a poly(ADP-ribose) polymerase inhibitor may improve outcomes, especially in pMMR disease.

METHODS This phase III, global, double-blind, placebo-controlled trial randomly assigned eligible patients with newly diagnosed advanced or recurrent endometrial cancer 1:1:1 to: carboplatin/paclitaxel plus durvalumab placebo followed by placebo maintenance (control arm); carboplatin/paclitaxel plus durvalumab followed by maintenance durvalumab plus olaparib placebo (durvalumab arm); or carboplatin/paclitaxel plus durvalumab followed by maintenance durvalumab plus olaparib (durvalumab + olaparib arm). The primary end points were progression-free survival (PFS) in the durvalumab arm versus control and the durvalumab + olaparib arm versus control.

RESULTS Seven hundred eighteen patients were randomly assigned. In the intention-to-treat population, statistically significant PFS benefit was observed in the durvalumab (hazard ratio [HR], 0.71 [95% CI, 0.57 to 0.89]; P = .003) and durvalumab + olaparib arms (HR, 0.55 [95% CI, 0.43 to 0.69]; P < .0001) versus control. Prespecified, exploratory subgroup analyses showed PFS benefit in dMMR (HR [durvalumab v control], 0.42 [95% CI, 0.22 to 0.80]; HR [durvalumab + olaparib v control], 0.41 [95% CI, 0.21 to 0.75]) and pMMR subgroups (HR [durvalumab v control], 0.77 [95% CI, 0.60 to 0.97]; HR [durvalumab + olaparib v control] 0.57; [95% CI, 0.44 to 0.73]); and in PD-L1–positive subgroups (HR [durvalumab v control], 0.63 [95% CI, 0.48 to 0.83]; HR [durvalumab + olaparib v control], 0.42 [95% CI, 0.31 to 0.57]). Interim overall survival results (maturity approximately 28%) were supportive of the primary outcomes (durvalumab v control: HR, 0.77 [95% CI, 0.56 to 1.07]; P = .120; durvalumab + olaparib v control: HR, 0.59 [95% CI, 0.42 to 0.83]; P = .003). The safety profiles of the experimental arms were generally consistent with individual agents.

CONCLUSION Carboplatin/paclitaxel plus durvalumab followed by maintenance durvalumab with or without olaparib demonstrated a statistically significant and clinically meaningful PFS benefit in patients with advanced or recurrent endometrial cancer.

ACCOMPANYING CONTENT
Listen to the podcast by Dr Schapira, Dr Westin, and Dr Eskander at jcopodcast.libsyn.com
Appendix
Data Sharing Statement
Data Supplement
Protocol

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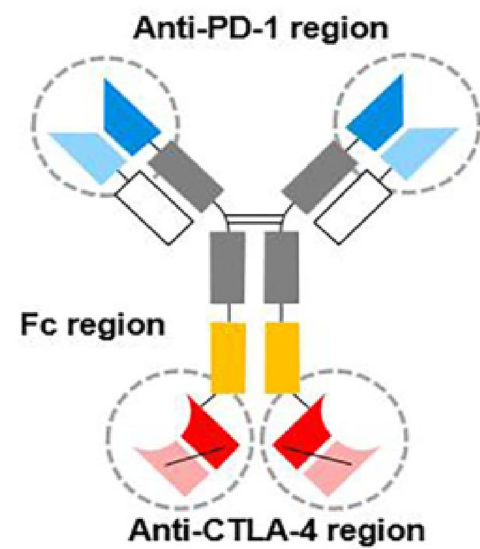
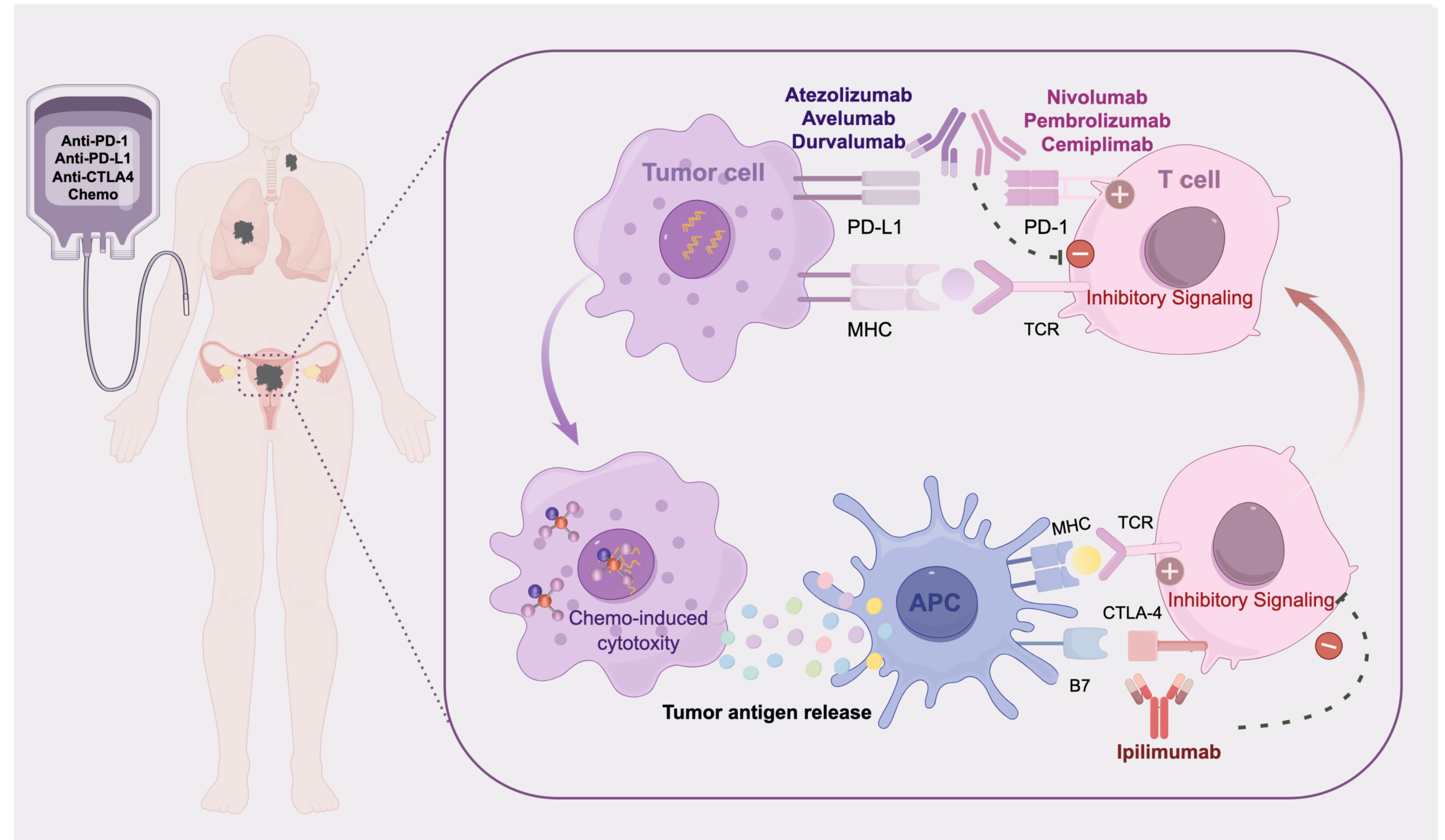
Background



Cadonilimab



- A humanized bi-specific antibody that binds to PD-1 and CTLA-4 simultaneously.
- Scafold Fc-engineered design could minimise lymphocyte loss and antibody-dependent cytokine release.

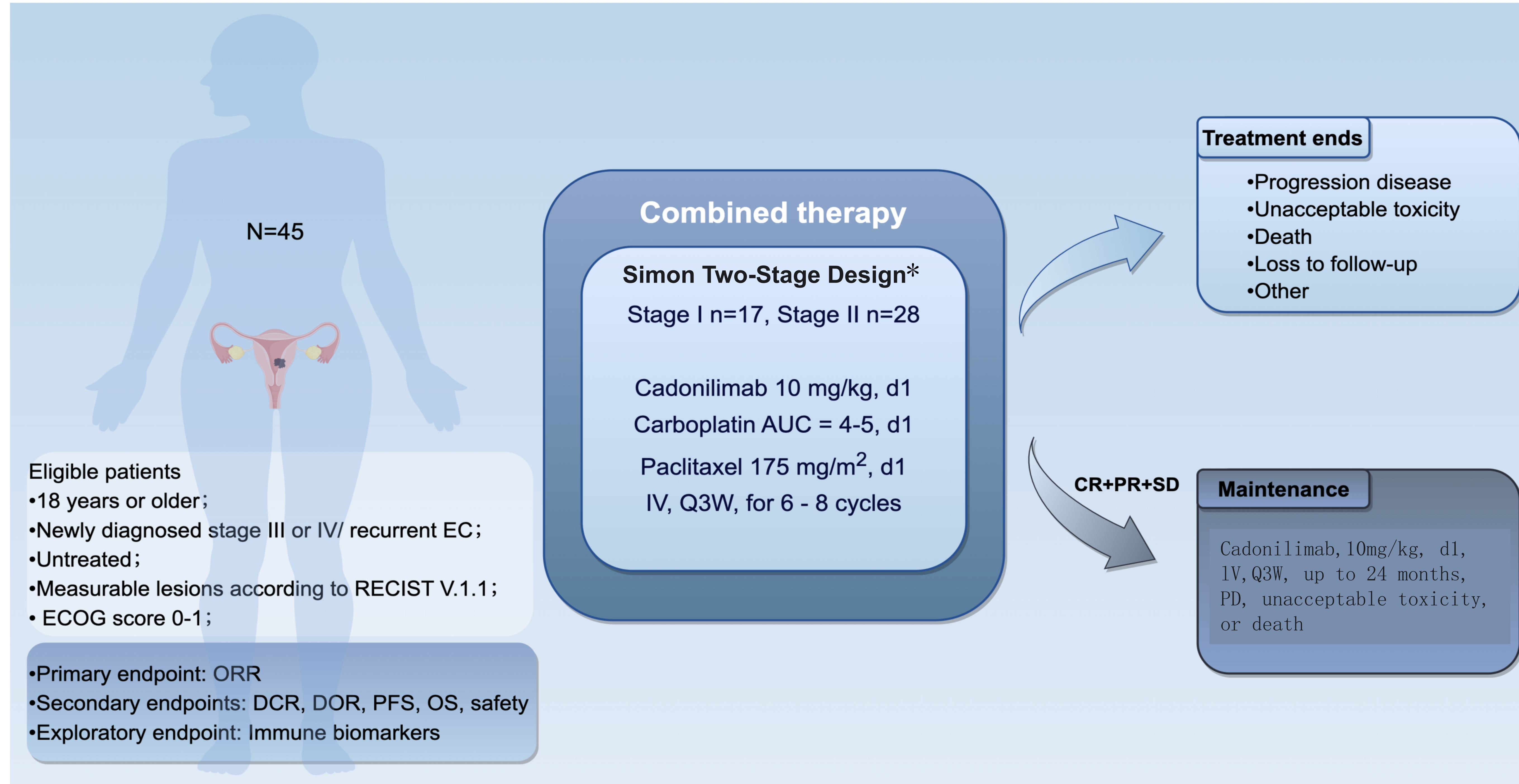
Inspiration

Could an anti-PD-1/CTLA-4 bi-specific antibody provide clinical benefits in the first-line setting?

We conducted a multicenter, single-arm, phase II trial to evaluate cadonilimab combined with chemotherapy as the first-line treatment for advanced/recurrent endometrial cancer

Study design

- **CARE Trial _Cadonilimab and Chemotherapy in Endometrial Cancer (NCT06066216)**



* If more than 7 patients in stage I respond to the therapy, the trial will proceed to stage II.

Results

- **Enrollment: From Dec 28, 2023 to Dec 29, 2025**
- **Data cut-off date: Feb 28, 2026**
- **Median followed-up: 10.9 months (8.8, 13.0)**

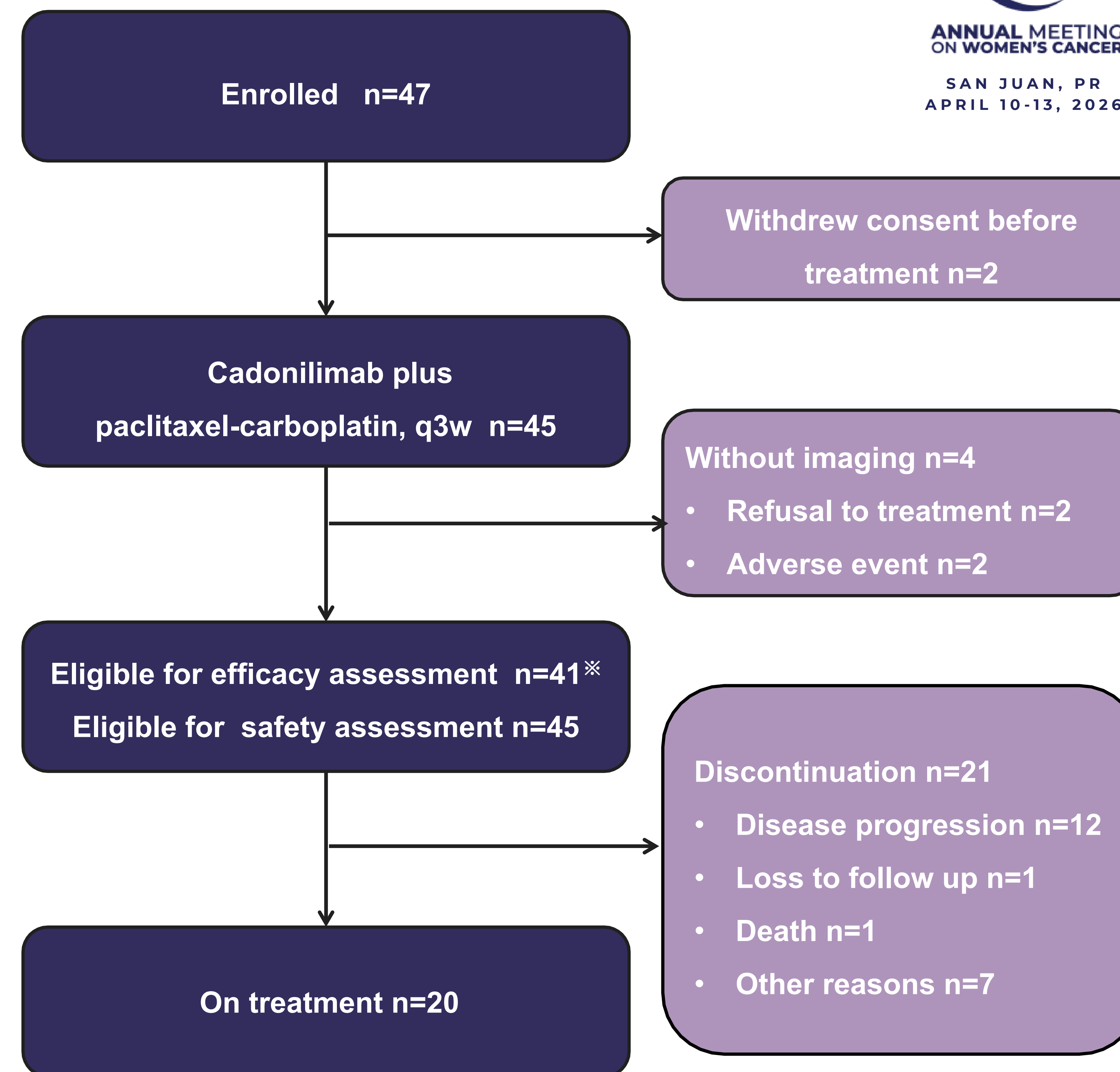


Figure 1 Patient flow diagram

※Four patients could not be evaluated due to the absence of their images.

Baseline characteristics

Characteristic	n=45
Age, years, median (range)	60(49-75)
Disease status, No. (%)	
Newly diagnosed FIGO stage III	6(13.33)
Newly diagnosed FIGO stage IV	15(33.33)
Recurrent	24(53.33)
Histology type, No. (%)	
Endometrioid	30(66.67)
Serous	7(15.56)
Others	8(17.78)
MMR status, No. (%)	
Proficient	36(80)
Deficient	9(20)

Objective response rate

Efficacy	FAS n=45	Efficacy Evaluable Set n=41
ORR, % (95% CI)	71.1 (56.6 to 82.3)	78.0 (63.3 to 88.0)
DCR, % (95% CI)	88.9 (76.5 to 95.2)	97.6 (87.4 to 99.9)
Best overall response		
CR	1	1
PR	31	31
SD	8	8
PD	1	1
Not evaluable	4	-

Abbreviations: FAS, Full analysis set; ORR, Objective response rate; DCR, Disease control rate; CR, Complete response; PR, Partial response; SD, Stable disease; PD, Progressive disease.

In stage I , 12 out of 17 patients achieved either complete response (CR) or partial response (PR) and the trial proceeded to stage II.

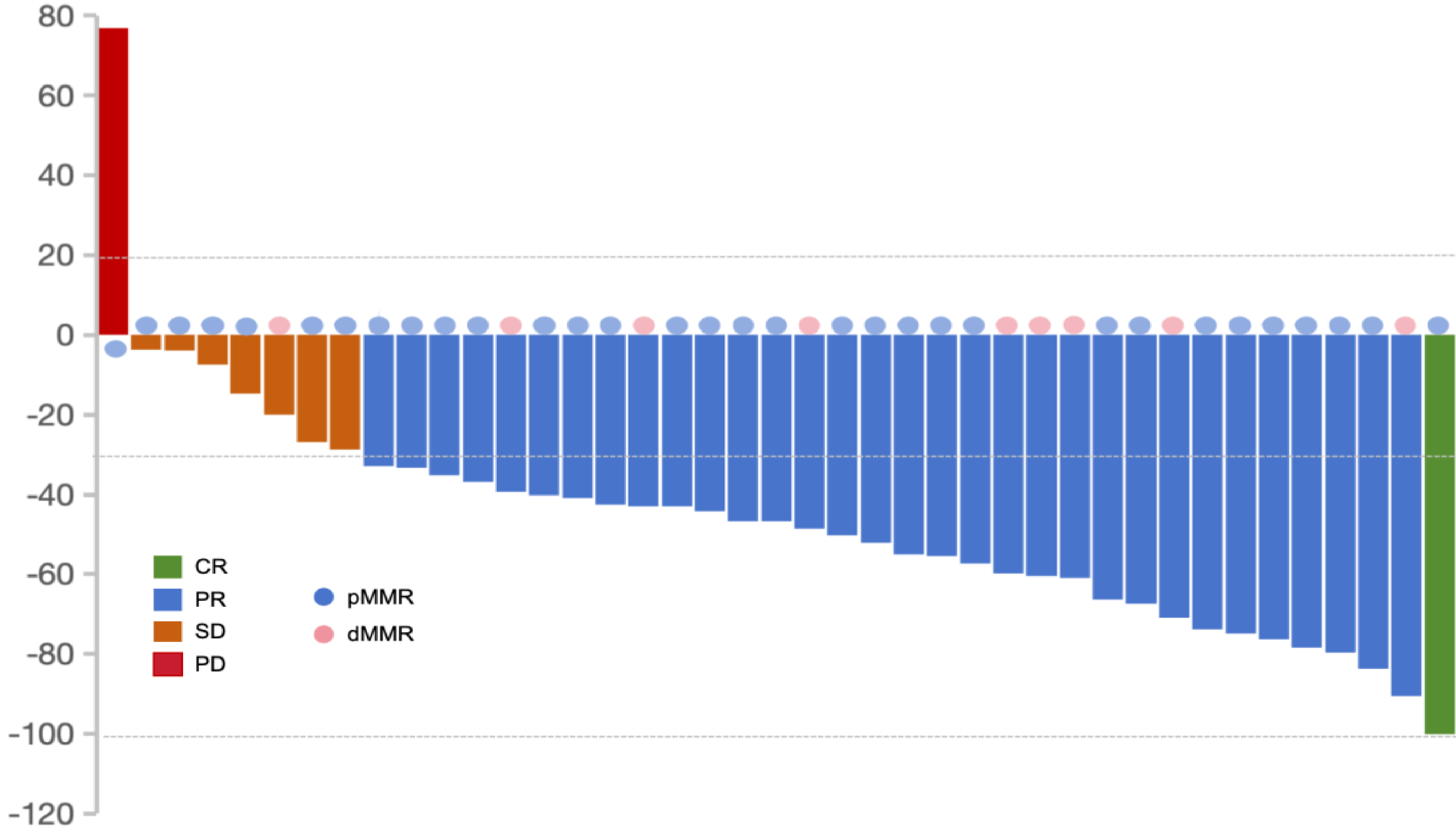


Figure 2 Waterfall plot depicting the best change in target lesion size from baseline.

Efficacy in each patients

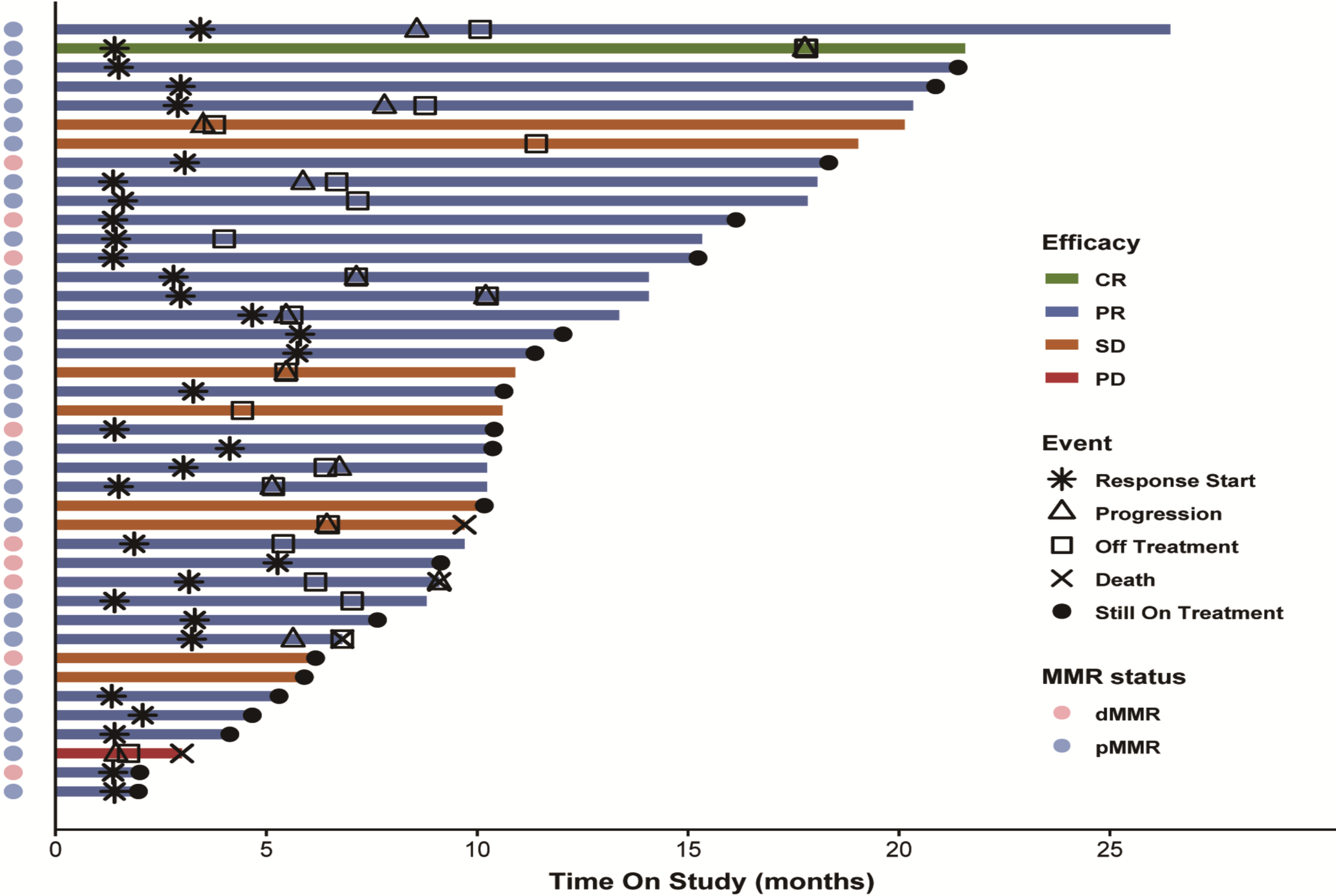
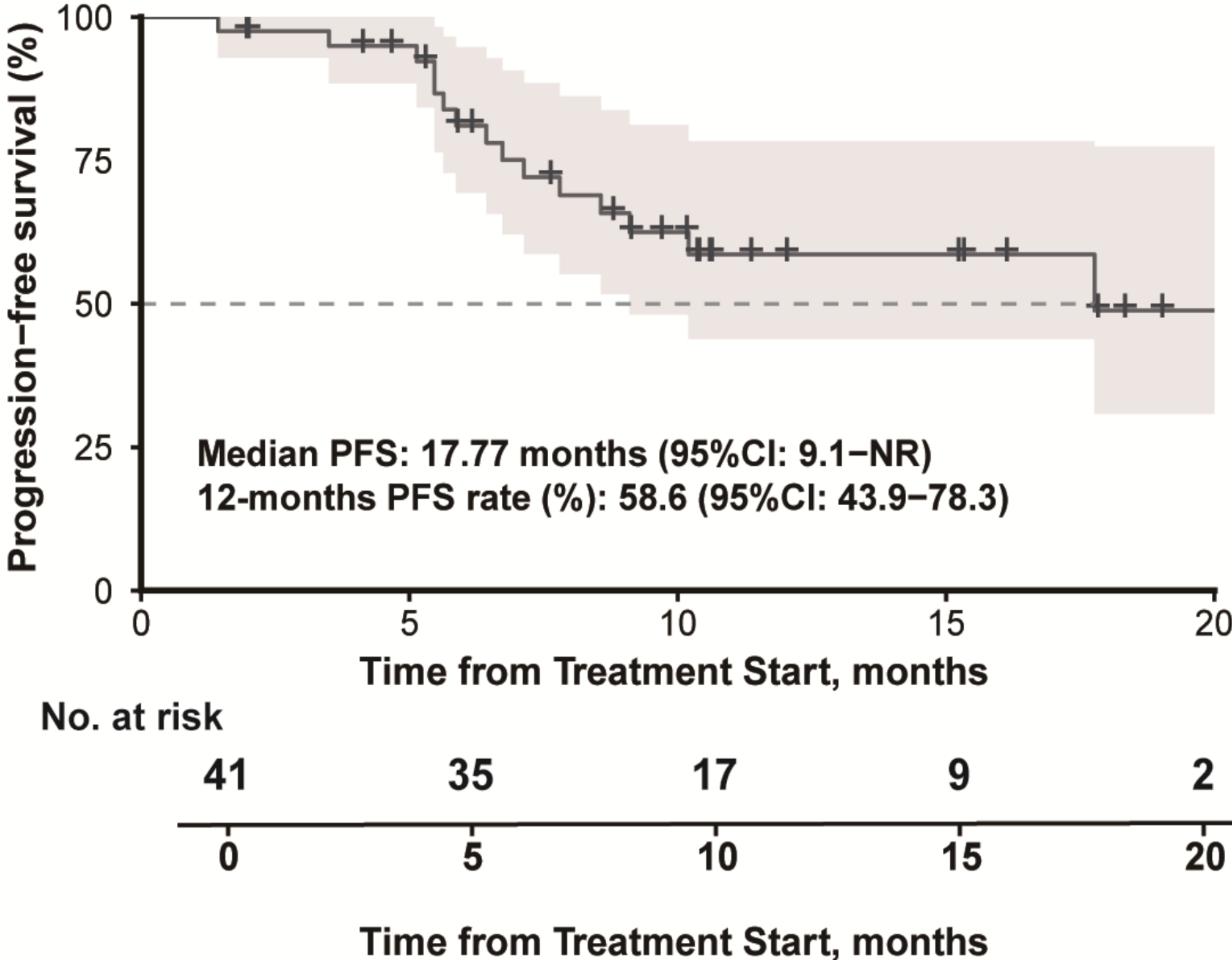
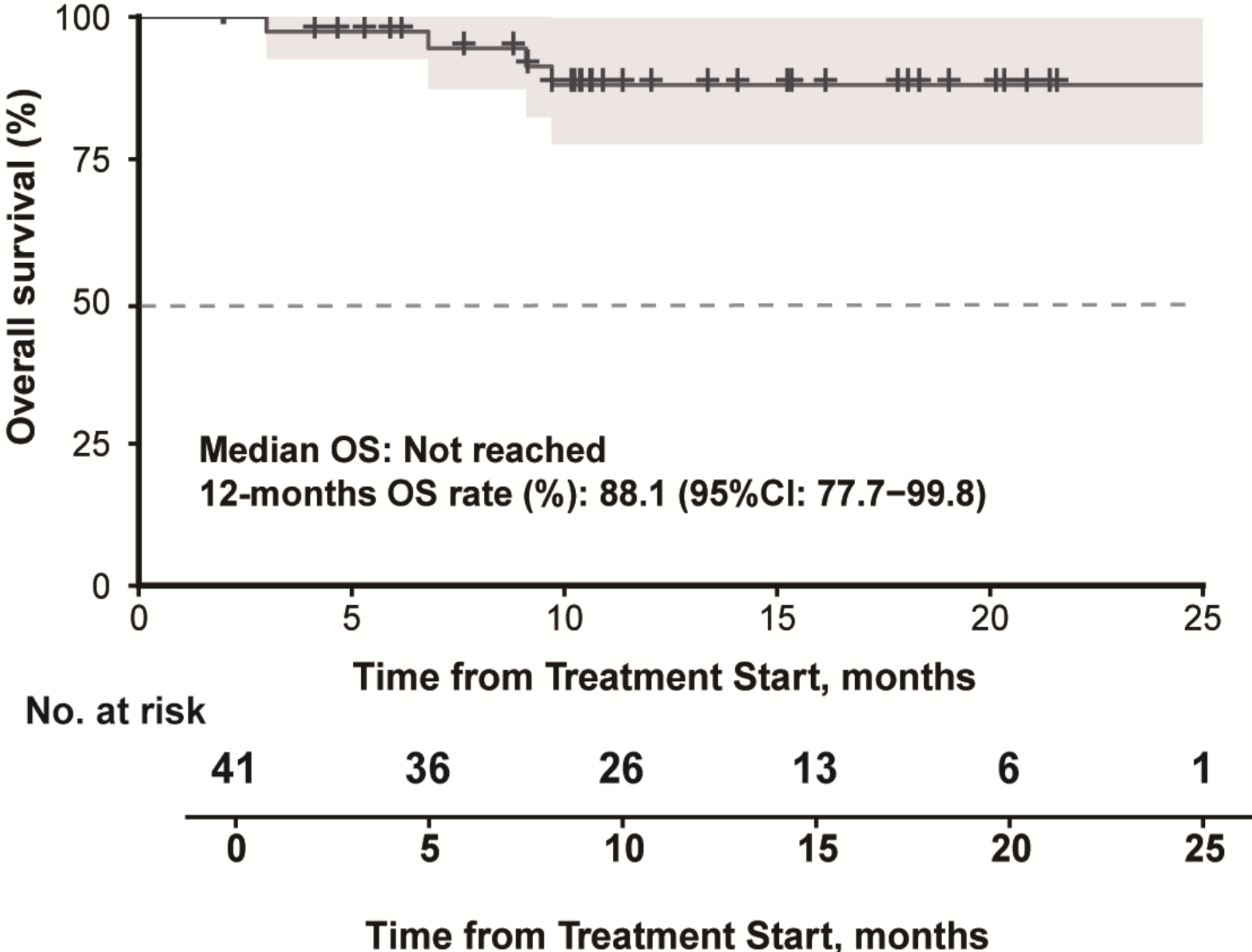


Figure 3 The swimmer plot.

Survival outcomes



PFS



OS

Subgroup analysis

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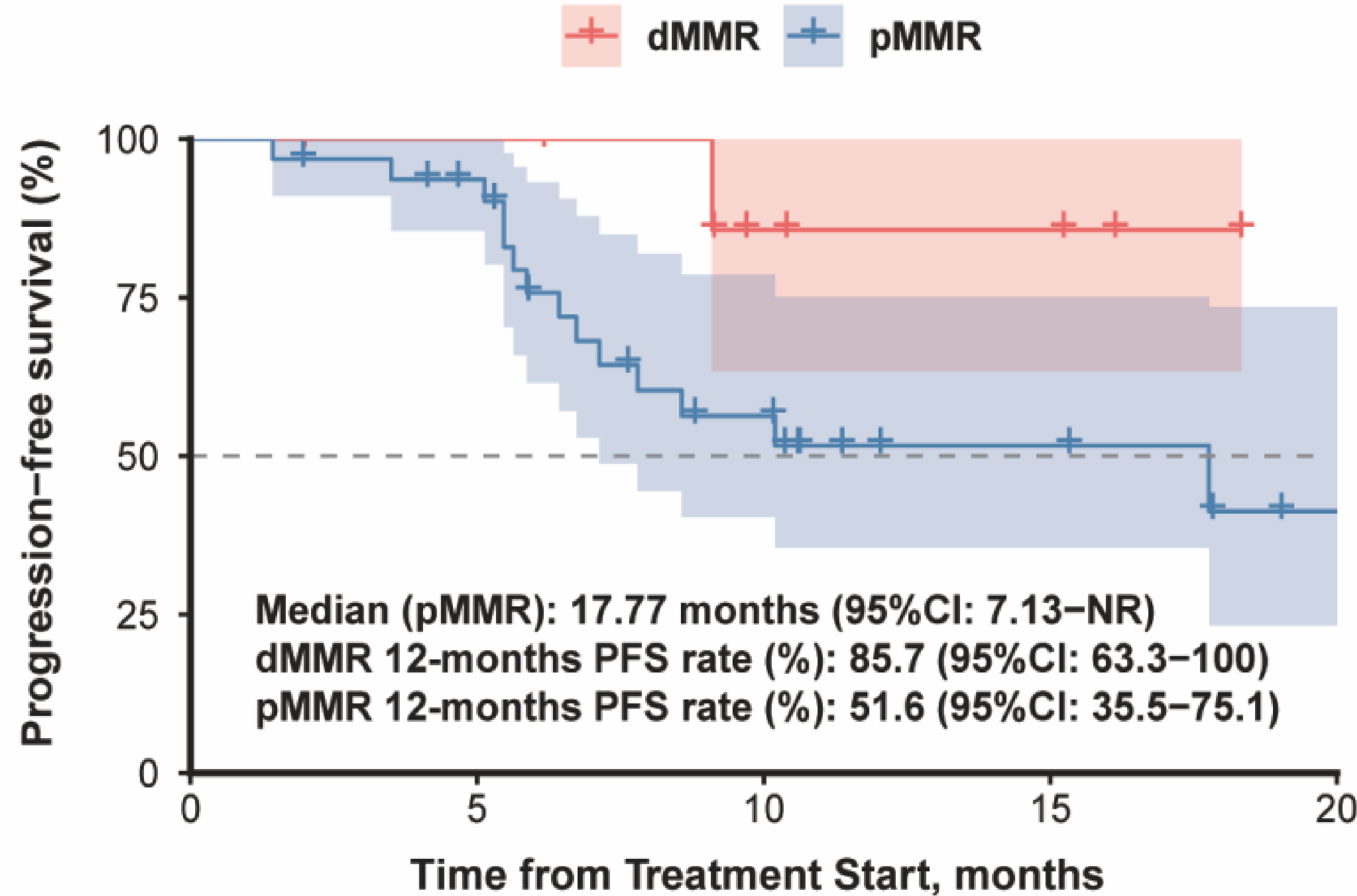
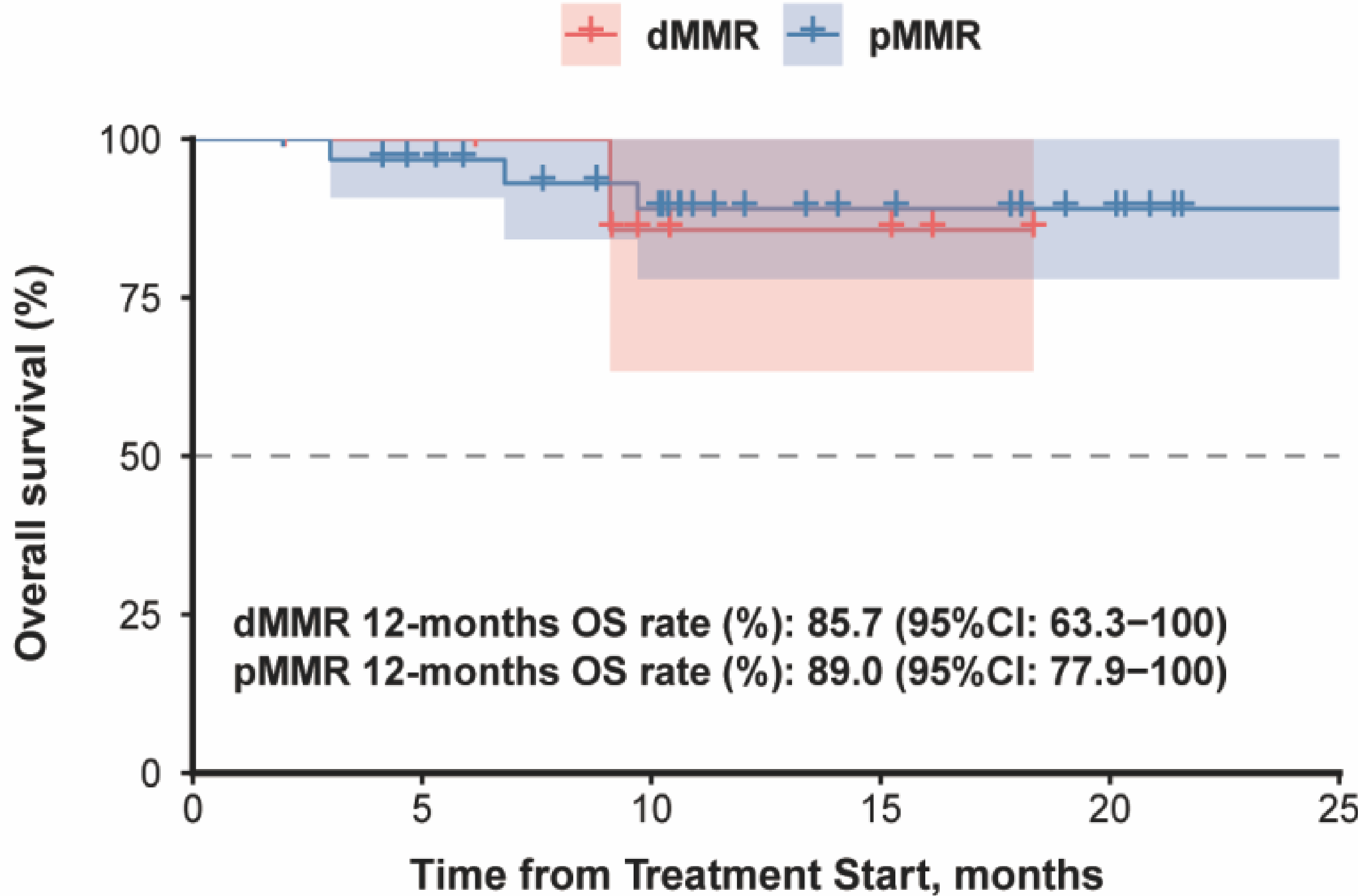


PFS



OS

TRAEs

- **17.8% (8/45) of patients experienced the Grade 3-4 TRAEs.**
- **None Grade 5 TRAEs.**

- **Rash: 4.4% (2/45)**
- **Allergy: 4.4% (2/45)**
- **Adrenal insufficiency: 2.2% (1/45)**
- **Hyperglycemia: 2.2% (1/45)**
- **Myelosuppression: 2.2% (1/45)**
- **Hypokalemia: 2.2% (1/45)**

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Conclusion

- **Cadonilimab combined with chemotherapy showed promising antitumor activity as the first-line treatment for advanced/recurrent endometrial cancer.**

- **The combination therapy had a favorable and manageable safety profile.**

Acknowledgements

- We would like to express our heartfelt gratitude to our patients and their families. They are our "why", and we will continue to work to advance the treatment landscape and transform the standard of care for their behalf.

- We also extend our special thanks to our sites, research teams, and investigators.

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Fujian Cancer Hospital	Yang Sun
Jiangsu Cancer Hospital	Xiaoxiang Chen
Zhangzhou Affiliated Hospital of Fujian Medical University	Yanhong Zhuo
Yunnan Cancer Hospital	Linlin Yang
The First Affiliated Hospital of Bengbu Medical University	Yuzhi Li

- Principal investigator: Yang Sun
- Study design: Yang Sun
- This study was sponsored by Akeso, Inc.

福建省肿瘤医院

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