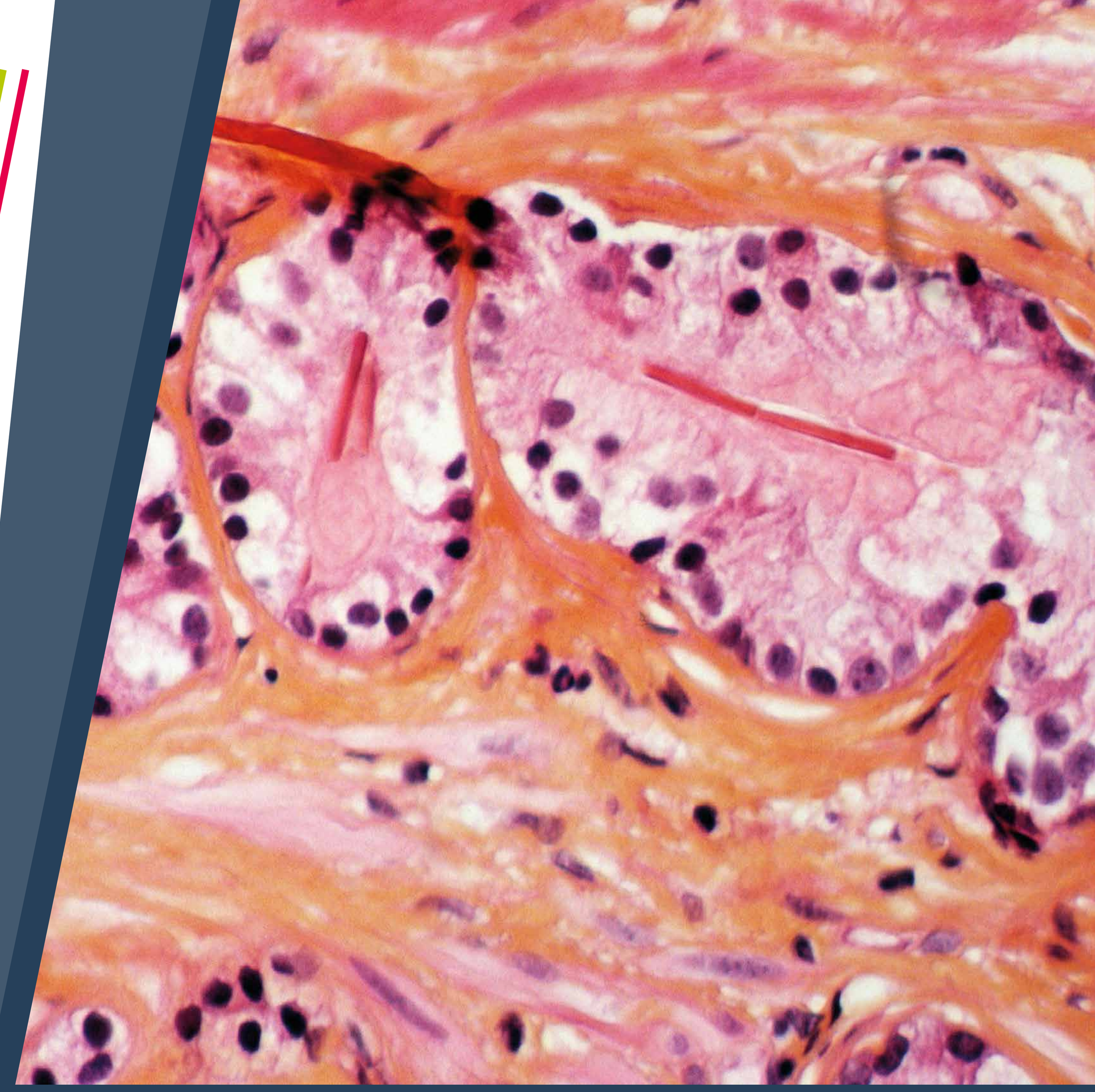
DAROLUTAMIDE

PROSTATE-SPECIFIC ANTIGEN RESPONSE WITH DAROLUTAMIDE PLUS ANDROGEN-DEPRIVATION THERAPY IN PATIENTS WITH METASTATIC HORMONE-SENSITIVE PROSTATE CANCER IN ARANOTE

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INTRODUCTION

In the phase 3 ARANOTE study (NCT04736199), darolutamide + ADT reduced the risk of radiological progression or death by 46% (HR 0.54; 95% CI 0.41–0.71; *P*<0.0001) versus placebo + ADT in patients with mHSPC[1]

The incidence of treatment-emergent adverse events was low and similar between groups[1]

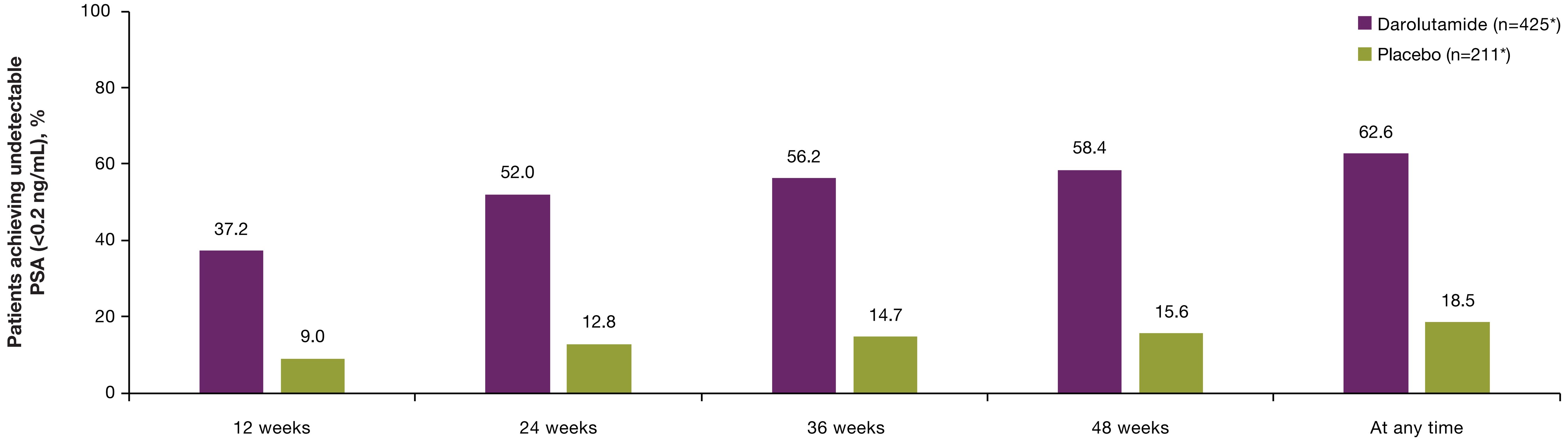
Patients achieving undetectable PSA (<0.2 ng/mL) at any time had better ECOG performance status, lower Gleason score, and lower baseline PSA values versus patients who did not

METHODS

We report post-hoc analyses of ARANOTE correlating PSA response with outcomes overall and by baseline PSA level

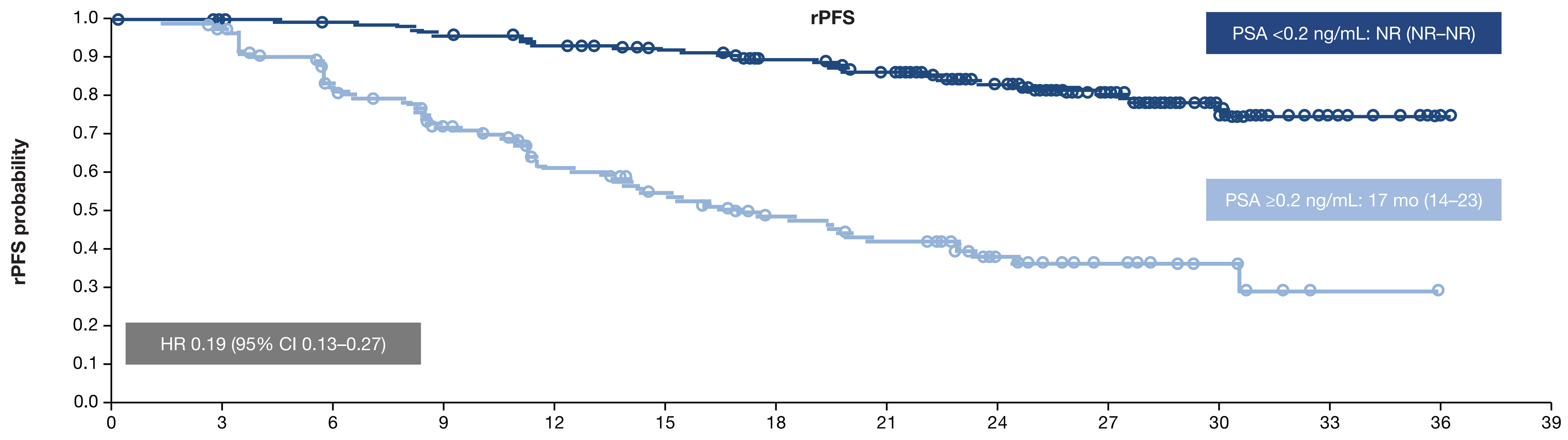
Darolutamide resulted in a deep PSA response

Three times as many patients achieved undetectable PSA (<0.2 ng/mL) at any time vs those on placebo


Patients achieving undetectable PSA (<0.2 ng/mL), %
100
80
60
40
20
0
Darolutamide (n=425*)
Placebo (n=211*)
37.2
9.0
52.0
12.8
56.2
14.7
58.4
15.6
62.6
18.5
12 weeks
24 weeks
36 weeks
48 weeks
At any time

*Excludes patients with undetectable PSA (<0.2 ng/mL) at baseline (darolutamide n=11; placebo n=8). PSA, prostate-specific antigen.

Patients on darolutamide who achieved undetectable PSA (<0.2 ng/mL) had a lower risk of radiological progression or death


rPFS
rPFS probability
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
PSA <0.2 ng/mL: NR (NR–NR)
PSA ≥0.2 ng/mL: 17 mo (14–23)
HR 0.19 (95% CI 0.13–0.27)
0
3
6
9
12
15
18
21
24
27
30
33
36
39
Time, months

Number of patients at risk

	0	3	6	9	12	15	18	21	24	27	30	33	36	39
PSA <0.2 ng/mL	266	263	260	252	243	234	222	208	147	90	43	8	1	0
PSA ≥0.2 ng/mL	159	138	107	85	67	55	43	36	24	13	6	1	0	0

CI, confidence interval; HR, hazard ratio; mo, months; NR, not reached; PSA, prostate-specific antigen; rPFS, radiological progression-free survival.
Reprinted from Saad F, et al. Eur Urol Oncol. 2025. https://doi.org/10.1016/j.euo.2025.06.010, with permission from Elsevier.

CONCLUSIONS

- Darolutamide provided deep and durable PSA responses in the overall population and across baseline PSA subgroups
- Undetectable PSA with darolutamide correlated with clinical benefit in terms of radiological progression or death and longer times to mCRPC and PSA progression
- The safety profile of darolutamide was consistent across subgroups, regardless of PSA response and baseline PSA

SCAN ME FOR MORE INFO

Reference: 1. Saad F, et al. J Clin Oncol 2024;42(36):4271–81.

ADT, androgen-deprivation therapy; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen.

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