Association Between Patient-Reported Outcomes and Changes in Prostate-Specific Antigen in Patients With Advanced Prostate Cancer Treated With Apalutamide in the SPARTAN and TITAN Studies

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INTRODUCTION

- In phase 3 placebo (PBO) controlled trials using androgen deprivation therapy (ADT),[1-4] the addition of apalutamide (APA) in patients with nonmetastatic castration-resistant prostate cancer (nmCRPC; SPARTAN) and metastatic castration-sensitive prostate cancer (mCSPC; TITAN) resulted in:
  - Improved overall survival;
  - Reduced risk of disease progression;
  - Preserved health-related quality of life (HRQoL).
- In many patients, prostate-specific antigen (PSA) responses were rapid and deep, with reduction to ≤ 0.2 ng/mL or ≥ 90% reduction compared with baseline.[5]
- Reduction was associated with extended metastasis-free survival (MFS; SPARTAN) or radiographic progression-free survival (rPFS; TITAN).[5]
- The objective of this post hoc analysis of SPARTAN and TITAN was to explore the relationship between rapid and deep PSA decline with HRQoL following APA treatment.

METHODS

- Patients were randomized to 28-day cycles of APA (240 mg QD) or PBO.
  - SPARTAN 2:1 (N = 1207; APA n = 806), TITAN 1:1 (N = 1052; APA n = 525).
- Patient-reported outcomes (PROs) were assessed at baseline, specific cycles during treatment, and post progression up to 1 year via paper (SPARTAN) or electronic (TITAN) surveys:
  - Functional Assessment of Cancer Therapy-Prostate (FACT-P) ;
  - Brief Pain Inventory-Short Form (BPI-SF; TITAN only);
  - Brief Fatigue Inventory (BFI; TITAN only).
- A Month 3 landmark analysis and a Month 6 landmark analysis evaluated PSA decline (≤ 0.2 ng/mL) and time to subsequent deterioration in PROs (≥ 10 points in FACT-P total, ≥ 3 points in Physical Wellbeing, ≥ 30% baseline from the BPI-SF worst pain, or ≥ 2 points for BFI worst fatigue).
  - Only patients who continued treatment were included; survival estimates were conditional on patient group membership at the time of landmark.
- Time-to-event end points were analyzed by Kaplan-Meier method and Cox proportional hazards model.
- Baseline characteristics are listed in the supplemental table.

Find out more

RESULTS

Treatment follow-up time, treatment duration, and completed PROs

	SPARTAN[2]	TITAN[4]
Median follow-up time (months)	52.0	44.0
Median treatment duration (months)		
APA	32.9	39.3
PBO	11.5	20.2
Completed PROs[a]		
FACT-P	> 90%	> 50%
BPI-SF	N/A	> 62%
BFI	N/A	> 62%

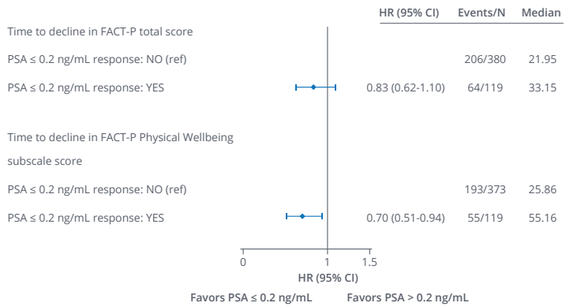
[a]TITAN, Cycles 1-81; SPARTAN, Cycles 1-33.

PROSTATE CANCER

RESULTS

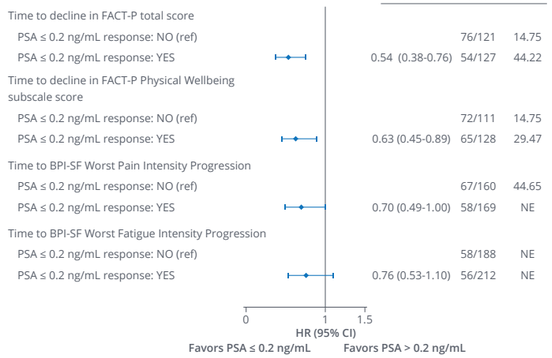
SPARTAN, nmCRPC

At Month 3, PSA decline correlated with HRQoL measures

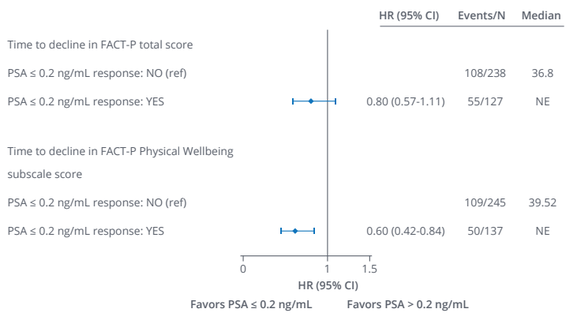


TITAN, mCSPC

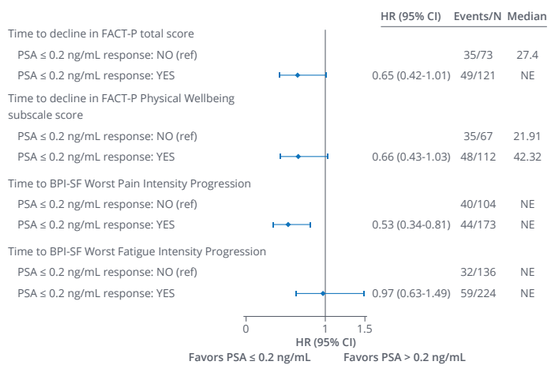
At Month 3, PSA decline correlated with HRQoL measures



At Month 6, PSA decline correlated with HRQoL measures



At Month 6, PSA decline correlated with HRQoL measures



NE, not estimable.

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KEY TAKEAWAY

Patients with advanced prostate cancer who had rapid and deep declines in PSA following treatment with APA had more favorable HRQoL, physical wellbeing, and less pain and fatigue.

These data may help guide care of and counsel for patients with nmCRPC or mCSPC.

CONCLUSIONS

Patients with advanced prostate cancer treated with APA in SPARTAN and TITAN had rapid and deep PSA declines that were associated with

- Maintenance of HRQoL;
- Improved patient-reported physical wellbeing;
- Reduced risk of worsening pain and fatigue intensity.

These data show that early PSA response indicates benefits in patient-relevant end points in conjunction with oncological outcomes.

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