

Supplementary material for:

# Evaluation of Concomitant Medications in Advanced Prostate Cancer Patients Receiving Apalutamide: TITAN and SPARTAN Post-Hoc Analysis

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# Supplementary Table 1: Baseline characteristics

Participants, n (%) or median (range)	TITAN				SPARTAN			
	Safety population		Any conmed <sup>a</sup>		Safety population		Any conmed <sup>a</sup>	
	APA + ADT (n=525)	PBO + ADT (n=527)	APA + ADT (n=351)	PBO + ADT (n=320)	APA + ADT (n=806)	PBO + ADT (n=401)	APA + ADT (n=589)	PBO + ADT (n=273)
Age, years	69 (45–94)	68 (43–90)	69 (45–94)	69 (43–90)	74 (48–94)	74 (52–97)	75 (49–92)	74 (52–96)
Race								
White	354 (67.4)	365 (69.3)	234 (68.2)	221 (69.9)	524 (65.0)	276 (68.8)	388 (65.9)	190 (69.6)
Asian	119 (22.7)	110 (20.9)	80 (23.3)	63 (19.9)	93 (11.5)	47 (11.7)	48 (8.1)	24 (8.8)
Black/African American	10 (1.9)	9 (1.7)	8 (2.3)	7 (2.2)	48 (6.0)	20 (5.0)	42 (7.1)	17 (6.2)
Time from initial diagnosis to randomization, months (TITAN) or years (SPARTAN)	4.1 (0.5–222.9)	4.0 (0.7–341.4)	4.57 (0.5–222.9)	4.16 (0.7–341.4)	7.95 (0.3–30.4)	7.85 (0.8–26.3)	8.48 (0.3–28.4)	8.24 (0.8–26.3)
Tumor stage at diagnosis	n=525	n=527	n=351	n=320	n=794	n=394	n=579	n=268
T0	1 (0.2)	0	1 (0.3)	0	0	0	0	0
T1	41 (7.8)	27 (5.1)	28 (8.0)	17 (5.3)	141 (17.8)	63 (16.0)	105 (18.1)	45 (16.8)
T2	146 (27.8)	110 (20.9)	97 (27.6)	67 (20.9)	265 (33.4)	123 (31.2)	198 (34.2)	88 (32.8)
T3	210 (40.0)	225 (42.7)	147 (41.9)	129 (40.3)	296 (37.3)	163 (41.4)	213 (36.8)	107 (39.9)
T4	76 (14.5)	105 (19.9)	41 (11.7)	67 (20.9)	32 (4.0)	16 (4.1)	17 (2.9)	12 (4.5)
TX	51 (9.7)	60 (11.4)	37 (10.5)	40 (12.5)	60 (7.6)	29 (7.4)	46 (7.9)	16 (6.0)
Lymph node stage at diagnosis	n=525	n=527	n=351	n=320	n=799	n=395	n=582	n=269
N0	212 (40.4)	216 (41.0)	154 (43.9)	127 (39.7)	550 (68.8)	273 (69.1)	402 (69.1)	193 (71.7)
N1	199 (37.9)	184 (34.9)	122 (34.8)	108 (33.8)	118 (14.8)	61 (15.4)	83 (14.3)	37 (13.8)
NX	114 (21.7)	127 (24.1)	75 (21.4)	85 (26.6)	131 (16.4)	61 (15.4)	97 (16.7)	39 (14.5)
PSA doubling time, months	NA	NA	NA	NA	4.40 (0.8–10.0)	4.50 (0.7–10.0)	4.40 (0.8–10.0)	4.40 (0.7–9.9)
ECOG performance status	n=525	n=527	n=351	n=320	n=806	n=400	n=589	n=273
0	328 (62.5)	348 (66.0)	225 (64.1)	209 (65.3)	623 (77.3)	311 (77.8)	452 (76.7)	209 (76.6)
1	197 (37.5)	178 (33.8)	126 (35.9)	110 (34.3)	183 (22.7)	89 (22.3)	137 (23.3)	64 (23.4)
2	0	1 (0.2)	0	1 (0.3)	0	0	0	0
Baseline PSA, ng/mL	5.97 (0–2682)	4.02 (0–2229)	5.43 (0–2682)	3.77 (0–1882)	7.78 (0.1–294.8)	7.96 (1.1–291.8)	7.80 (0.3–294.8)	7.13 (1.1–291.8)
Extent of disease at study entry								
Bone	525 (100)	527 (100)	351 (100)	320 (100)	NA	NA	NA	NA
Bone only	289 (55.0)	269 (51.0)	195 (55.6)	164 (51.3)	NA	NA	NA	NA
Lymph node	199 (37.9)	219 (41.6)	129 (36.8)	129 (40.3)	NA	NA	NA	NA
Visceral	56 (10.7)	72 (13.7)	39 (11.1)	46 (14.4)	NA	NA	NA	NA
Soft tissue	22 (4.2)	27 (5.1)	13 (3.7)	18 (5.6)	NA	NA	NA	NA
Disease volume								
Low	200 (38.1)	192 (36.4)	138 (39.3)	117 (36.6)	NA	NA	NA	NA
High	325 (61.9)	335 (63.6)	213 (60.7)	203 (63.4)	NA	NA	NA	NA

<sup>a</sup>Among the 8 frequently used medication classes: antidiabetic, anticoagulant, antihypertensive, corticosteroid, gabapentinoid, macrolide, proton pump inhibitor, statin.

ADT, androgen deprivation therapy; APA, apalutamide; conmed, concomitant medication; ECOG, Eastern Cooperative Oncology Group; NR, not reported; PBO, placebo; PSA, prostate-specific antigen.



## Supplementary Table 2: Incidence rates of TEAEs influenced by DDIs<sup>a</sup> associated with concomitant antihypertensive<sup>b</sup> use in patients receiving APA versus those who did not receive APA (after adjusting for treatment exposure) in SPARTAN

	APA + ADT (n=344)		PBO + ADT (n=163)	
	Any grade TEAEs/100 PY <sup>c</sup>	Grade 3/4 TEAEs/100 PY <sup>c</sup>	Any grade TEAEs/100 PY <sup>c</sup>	Grade 3/4 TEAEs/100 PY <sup>c</sup>
Overall TEAEs	39.9	13.7	56.1	18.5
System organ class				
Preferred term				
Vascular disorders	29.5	12.5	40.9	17.4
Hypertension	26.3	12.3	37.6	17.4
Hypotension	2.8	0.2	2.2	0
Orthostatic hypotension	0.4	0	1.1	0
Metabolism and nutrition disorders	3.9	0.9	5.4	0.5
Hyperkalemia	2.4	0.5	1.6	0
Hypokalemia	0.4	0	2.2	0.5
Hypercalcemia	0	0	0.5	0
Hypocalcemia	0.3	0	0.5	0
Hyponatremia	0.8	0.4	0.5	0
Hypomagnesemia	0	0	0	0
Nervous system disorders	5.0	0.2	6.5	0
Dizziness	5.0	0.2	6.5	0
General disorders and administration site conditions	0.6	0	1.1	0
Peripheral swelling	0.6	0	1.1	0
Cardiac disorders	0.8	0.1	2.2	0.5
Tachycardia	0.7	0.1	0.5	0
Bradycardia	0.1	0	1.6	0.5

<sup>a</sup>Although preferred terms chosen for analysis of TEAEs associated with concomitant antihypertensives could be influenced by DDIs with APA, they could also be due to class effects of concomitant antihypertensive alone.

<sup>b</sup>Antihypertensive medications examined: angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, beta blockers, calcium channel blockers, and thiazide diuretics (including amlodipine, atenolol, bisoprolol, co-diovan, enalapril, hyzaar, lisinopril, losartan, metoprolol, nifedipine, ramipril, and valsartan).

<sup>c</sup>Exposure-adjusted incidence rates of TEAEs are expressed per 100 patient-years for the treatment group. Each rate is calculated by dividing the number of distinct TEAEs (overall or within a specified SOC or PT) by total patient-years of exposure (total exposure days divided by 365.25) and multiplying the result by 100.

ADT, androgen deprivation therapy; APA, apalutamide; PBO, placebo; PT, preferred term; PY, patient-year; SOC, system organ class; TEAE, treatment-emergent adverse event.



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