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Validation of Rapid and Deep Prostate-Specific Antigen Decline Among the Latin American Subgroup of LIBERTAS, a Phase 3 Study of Apalutamide Plus Continuous Versus Intermittent Androgen Deprivation Therapy in Metastatic Castration-Sensitive Prostate Cancer

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Key Takeaway

Rapid and deep PSA declines, that are a hallmark of APA + ADT, were seen in patients enrolled from Latin America, despite higher baseline PSA levels

Conclusions

- Patients enrolled in Latin America were younger and had more advance disease than the overall study population, demonstrating consistent deep PSA response regardless of differences in demographics and baseline clinical characteristics
- APA + ADT resulted in 96% of patients reaching PSA50 at 6 months, with 83% PSA90 and 61% PSA undetectable (PSA0.2) in this Latin American cohort
- The safety profile of APA remained consistent with prior experience

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Poster

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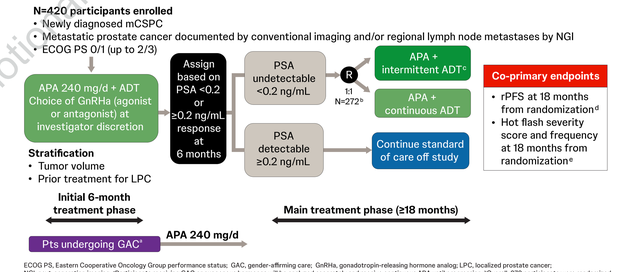
Introduction

- Apalutamide (APA) in combination with androgen deprivation therapy (ADT) showed rapid and deep prostate-specific antigen (PSA) decline in participants with metastatic castration-sensitive prostate cancer (mCSPC) in the phase 3 TITAN study, and this deep PSA decline was associated with improved overall survival (OS)[1]
- LIBERTAS is a global phase 3 study evaluating APA + intermittent ADT as an ADT de-escalation strategy for participants with mCSPC who achieve an undetectable PSA (<0.2 ng/mL) after 6 months on APA + continuous ADT
  - In the initial treatment phase, 6 months of APA + continuous ADT resulted in deep PSA responses in the majority of participants[2]
- Here, we present an analysis of the Latin American subgroup evaluating PSA responses following the initial treatment phase

Methods

- LIBERTAS (NCT05884398) is a phase 3, prospective, open-label, randomized study in participants with mCSPC (**Figure 1**)
- Participants with mCSPC were eligible if they had ≤3 months of prior ADT, ECOG PS 0–1, and confirmed metastases by conventional or next generation imaging
- In the initial 6-month treatment phase, all participants received APA 240 mg/day + ADT
- In the main treatment phase, participants with <0.2 ng/mL PSA were randomized 1:1 to APA 240 mg/day + intermittent or continuous ADT
- Co-primary endpoints: radiographic progression-free survival (rPFS), measured by the 18-month event-free survival rate; reduction of hot flash burden, measured by the 18-month severity-adjusted hot flash score

Figure 1: LIBERTAS study design



ECOG PS, Eastern Cooperative Oncology Group performance status; GAC, gender-affirming care; GnRHa, gonadotropin-releasing hormone analog; LPC, localized prostate cancer; NGI, next-generation imaging. [a]Participants receiving GAC or exogenous hormones will be analyzed separately and receive continuous APA until progression. [b]Overall, 272 participants were randomized including 1 participant without assignment of randomized treatment (intent-to-treat population n=271). [c]ADT may be restarted in the APA + intermittent ADT group for participants with new or worsening cancer symptoms, PSA increase to >10 ng/mL (or return to baseline level when PSA was <10 ng/mL before start of ADT), or PSA doubling time <8 months. [d]Radiographic progression assessed using conventional imaging. [e]Evaluated with Hot Flash Related Daily Interference Scale.

Results

Participants

- From December 2023 to July 2024, 118 participants from Latin America were enrolled, including 87 participants from 7 sites in Brazil, and 31 participants from 4 sites in Mexico
- Latin American participants were younger (median age 67 years) and had more advanced disease compared with the overall population (**Table 1**)
  - Among Latin American participants, 89.0% had M1 disease at diagnosis, 39.8% had ECOG PS1, and 66.1% had high volume disease
  - Median baseline PSA was 22.95 ng/mL compared with 7.32 ng/mL in the overall population

Table 1: Baseline demographics and disease characteristics

	Enrolled population	
	Latin American subgroup (N=118)	Overall study population (N=420)
Median (range) age, years	67.0 (48–86)	70.0 (48–88)
Gender identity, n (%)		
Man	92 (78.0)	370 (88.1)
Not Reported	26 (22.0)	50 (11.9)
Race, n (%)		
White	71 (60.2)	297 (70.7)
Asian	0	39 (9.3)
Black or African American	12 (10.2)	36 (8.6)
American Indian or Alaska Native	1 (0.8)	2 (0.5)
Other	21 (17.8)	22 (5.2)
Multiple	11 (9.3)	11 (2.6)
Not reported or unknown	2 (1.7)	13 (3.1)
Median (range) time from initial diagnosis to initial treatment, months	4.24 (1.0–171.2)	4.22 (0.5–265.6)
ECOG PS, n (%)[a]		
0	68 (57.6)	312 (74.3)
1	47 (39.8)	105 (25.0)
Subgroups of mCSPC, n (%)		
High volume	78 (66.1)	204 (48.6)
Low volume	40 (33.9)	216 (51.4)
Gleason score at initial diagnosis, n (%)[b]		
≤7	39 (33.1)	139 (33.1)
>7	75 (63.6)	269 (64.0)
Metastasis stage at diagnosis, n (%)[c]		
M0 or MX	13 (11.0)	146 (34.8)
M1	105 (89.0)	273 (65.0)
Visceral metastasis at study entry, n (%)	24 (20.3)	70 (16.7)
Liver metastases	3 (2.5)	7 (1.7)
Lung metastases	18 (15.3)	51 (12.1)
Median (range) baseline PSA, ng/mL	22.95 (0–4433.0)	7.32 (0–4433.0)

[a]ECOG 2 for 3 (0.7%) participants overall; all were Latin American. [b]Missing for 4 (3.4%) Latin American participants and for 12 (2.9%) participants overall. [c]Missing for 1 (0.2%) participant overall.

PSA decline

- Rapid and deep PSA decline was observed with APA+ADT in the majority of Latin American participants (**Figure 2**)
- Among 110 Latin American participants who completed the initial 6-month treatment phase, 105 (95.5%) achieved a ≥50% PSA decline (PSA50), 91 (82.7%) achieved a ≥90% PSA decline (PSA90), and 67 (60.9%) achieved PSA <0.2 ng/mL (PSA0.2) at any point during the first 6 months (**Figure 3**)
  - The proportions of participants achieving PSA decline were similar to those observed in the overall study population
- By 3 months of treatment, PSA50, PSA90, and PSA0.2 were achieved by 92.4%, 64.4%, and 29.7%, respectively, in Latin American participants (**Table 2**)
- Median time to achieve PSA50, PSA90, and PSA0.2 were 1.87 months, 1.91 months, and 3.14 months, respectively, in Latin American participants; these were similar to those in the overall study population
- A total of 62 Latin American participants who achieved PSA <0.2 ng/mL were randomized to the main treatment phase
  - There were 63 participants who had a confirmed PSA <0.2 ng/mL response at the 6 months visit (**Figure 2**); among these, one participant did not proceed to randomization as they discontinued the initial treatment phase due to an adverse event

Safety

- The safety profile in the Latin American subgroup was consistent with the global population, with no new safety signals (**Table 3**)

Figure 2: Confirmed PSA change (%) from baseline at 6 months among enrolled Latin American participants with PSA data at 6 months (n=111)

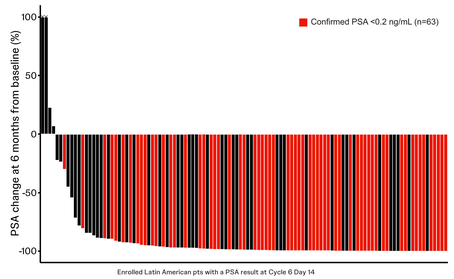


Figure 3: Confirmed PSA change (%) from baseline at 6 months among participants who completed the initial 6-months treatment phase with APA + ADT

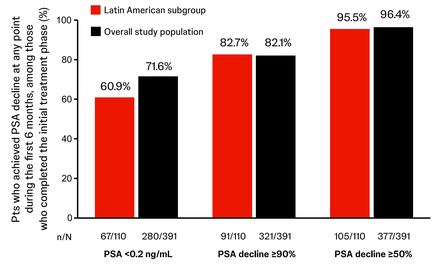


Table 2: Confirmed PSA decline after 3 months of treatment with APA + ADT, and median time to PSA decline during the initial treatment phase

	Enrolled population	
Confirmed PSA decline	Latin American subgroup (N=118)	Overall study population (N=420)
PSA decline after 3 months, n (%)		
PSA decline ≥50%	109 (92.4)	387 (92.1)
PSA decline ≥90%	76 (64.4)	281 (66.9)
PSA <0.2 ng/mL	35 (29.7)	196 (46.7)
Median (range) time to achieve confirmed PSA decline, months		
PSA decline ≥50%	1.87 (1.0–3.8)	1.87 (1.0–5.6)
PSA decline ≥90%	1.91 (1.1–15.7)	1.91 (1.1–18.4)
PSA <0.2 ng/mL	3.14 (1.8–5.5)	2.79 (1.5–5.7)

Table 3: Safety summary

	Safety population	
n (%)	Latin American subgroup (N=118)	Overall study population (N=420)
TEAEs	112 (94.9)	374 (89.0)
Treatment-related	81 (68.6)	295 (70.2)
Grade 3–4 TEAEs	29 (24.6)	84 (20.0)
Treatment-related	10 (8.5)	38 (9.0)
Serious AEs	12 (10.2)	37 (8.8)
Treatment-related	1 (0.8)	7 (1.7)
TEAEs leading to treatment discontinuation	6 (5.1)	20 (4.8)
Treatment-related	4 (3.4)	15 (3.6)
TEAEs leading to death	1 (0.8)	2 (0.5)
Treatment-related	0	0

AE, adverse event; TEAE, treatment-emergent adverse event.

References

1. Chowdhury S, et al. *Ann Oncol* 2023;34(5):477–485. **2.** Azad A, et al. *J Clin Oncol* 2025;43(5_suppl): Abstract 147.

Prostate Cancer

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