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KEY TAKEAWAYS

- The LIBERTAS results confirm that APA + ADT achieves rapid and deep PSA responses in Chinese patients with mCSPC and align with the pivotal TITAN Phase 3. APA's safety profile remains consistent with prior experience, supporting good tolerability in this population.

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CONCLUSIONS

- Chinese participants showed rapid and profound PSA responses to APA plus ADT, with 100% achieving PSA50, 97.2% achieving PSA90, and 61.1% reaching PSA0.2 by 6 months.
- The safety profile of apalutamide remained consistent with previous studies, supporting its tolerability in this population.
- These results confirm the efficacy of APA + ADT in Chinese mCSPC patients and are consistent with global findings.

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INTRODUCTION

- LIBERTAS is a global phase 3 study evaluating apalutamide (APA) plus intermittent versus continuous androgen deprivation therapy (ADT) in patients with metastatic castration-sensitive prostate cancer (mCSPC) [1].
- The study aims to determine if APA + intermittent ADT reduces the hot flash burden when compared with APA + continuous ADT and whether APA + intermittent ADT provides noninferior radiographic progression-free survival (rPFS).
- Initial findings demonstrated that treatment with 6 months of APA + ADT resulted in rapid and deep PSA responses in most patients with mCSPC.
- This analysis reports PSA response results from patients enrolled in China.

1. Azad A, et al. Deep PSA Decline in the Chinese Subgroup of LIBERTAS. Poster presented at ASCO GU 2025; 2025 Feb 13–15; San Francisco, CA.

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METHODS

- Overall, eligible mCSPC participants had ≤ 3 months of prior ADT, ECOG PS 0–1, and confirmed metastases by conventional or next-generation imaging.
- All received APA 240 mg/day + ADT during the initial 6-month treatment phase.
- In the main phase, 22 participants from China with PSA < 0.2 ng/mL were randomized 1:1 to continuous or intermittent ADT.
- Primary endpoints: reduction of hot flash burden, measured by severity-adjusted hot flash score, and rPFS, measured by 18-mo event-free survival rate (Figure 1).

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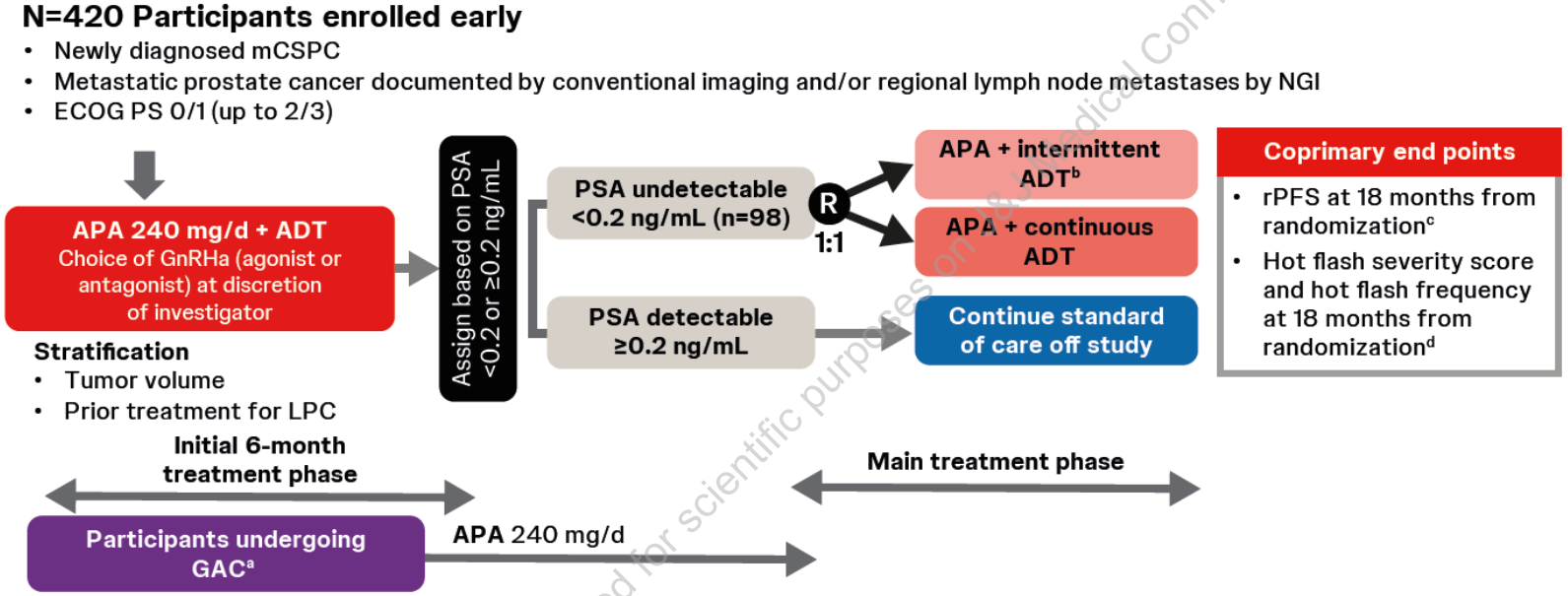
Figure 1: Early enrollment in LIBERTAS



[a]Participants undergoing GAC or with a variation in physical development who receive exogenous hormones will be evaluated as a separate cohort with regard to their outcomes in a descriptive manner. These participants will not be randomized for the main treatment phase and will be treated with APA continuously from study initiation until disease progression.
[b]ADT can 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 <6 months.
[c]Radiographic progression assessed using convention imaging.
[d]Hot flashes will be evaluated using the Hot Flash Related Daily Interference Scale Patient-Reported Outcome questionnaire.

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RESULTS

- Total 36 Chinese participants were enrolled, with 22 randomized to the main treatment phase.
- At baseline, participants had a median (range) age of 71 yrs (51-79) and median PSA 64.7 ng/ml (2.6-2399 ng/ml).
- Most participants (75.0%) presented with high-volume disease. The majority (88.9%) had a Gleason score greater than 7. Visceral metastases were observed in 33.3% of patients, primarily in the lungs, with no cases of liver metastases reported.
- Chinese subgroup demonstrated more severe baseline characteristics compared to the global population, including higher proportions of HV, Gleason score > 7, visceral metastases, and elevated median baseline PSA levels (Table 1).

Table 1: Baseline demographics and disease characteristics

	Enrolled	Randomized[a]
	N=36	N=22
Median (range) age, years	71.0 (51; 79)	69.5 (51; 79)
Gender identity, n (%)		
Man	27 (75.0%)	21 (95.5%)
Not Reported	9 (25.0%)	1 (4.5%)
Median (range) time from initial diagnosis to initial treatment, months	0.99 (0.5; 14.9)	0.97 (0.6; 14.9)
ECOG PS, n (%)		
0	26 (72.2%)	19 (86.4%)
1	10 (27.8%)	3 (13.6%)
Subgroups of mHSPC, n (%)		
High volume	27 (75.0%)	15 (68.2%)
Low volume	9 (25.0%)	7 (31.8%)
Gleason score at initial diagnosis, n (%)		
≤7	4 (11.1%)	2 (9.1%)
>7	32 (88.9%)	20 (90.9%)
Metastasis stage at diagnosis, n (%)		
M0 or MX	2 (5.6%)	2 (9.1%)
M1	34 (94.4%)	20 (90.9%)
Visceral metastases at study entry, n (%)	12 (33.3%)	9 (40.9%)
Liver metastases	0	0
Lung metastases	10 (27.8%)	7 (31.8%)
Median (range) baseline PSA, ng/mL	64.70 (2.6; 2399.0)	42.39 (2.6; 2399.0)

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Figure 2: Confirmed PSA change (%) at 6 months from baseline among enrolled participants with PSA data at 6 months (n=36)

- APA + ADT led to rapid and deep PSA decline in a majority of participants (Figure 2).

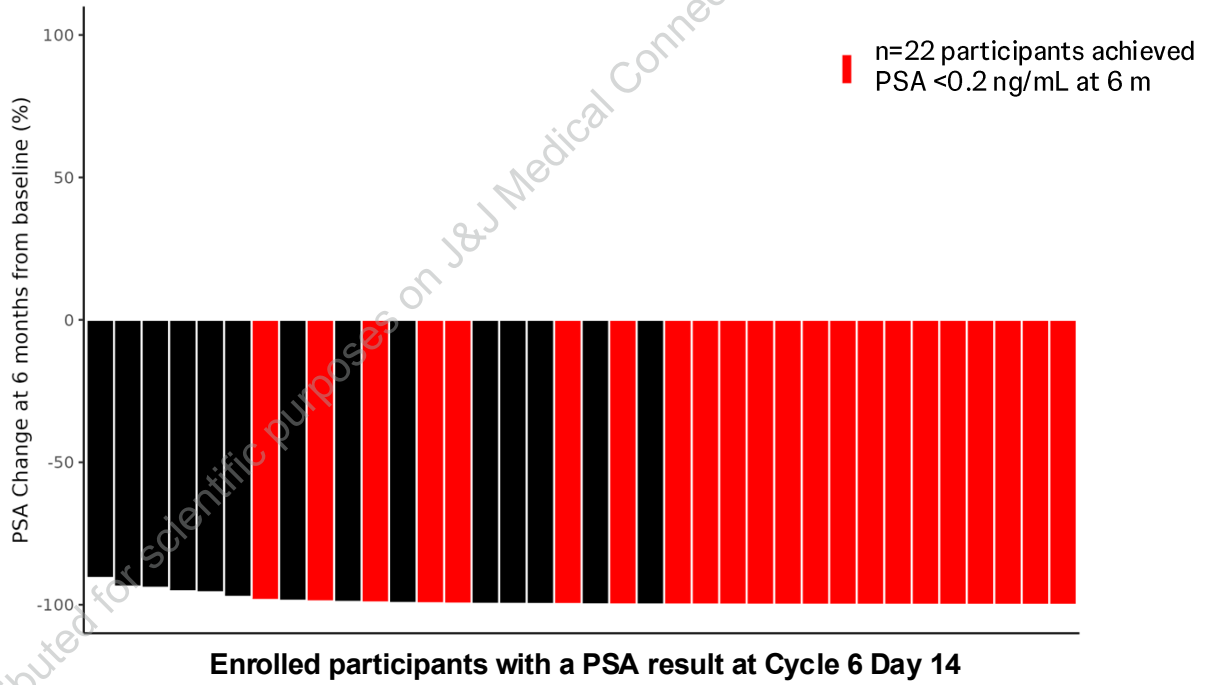

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Figure 3: Confirmed PSA decline among participants who completed the initial 6-month treatment phase with APA + ADT

- Among the participants who completed initial 6-month treatment phase, 100.0% and 97.2% achieved PSA decline from baseline ≥ 50% or ≥ 90%, respectively, 61.1% achieved PSA < 0.2 ng/mL (Figure 3).

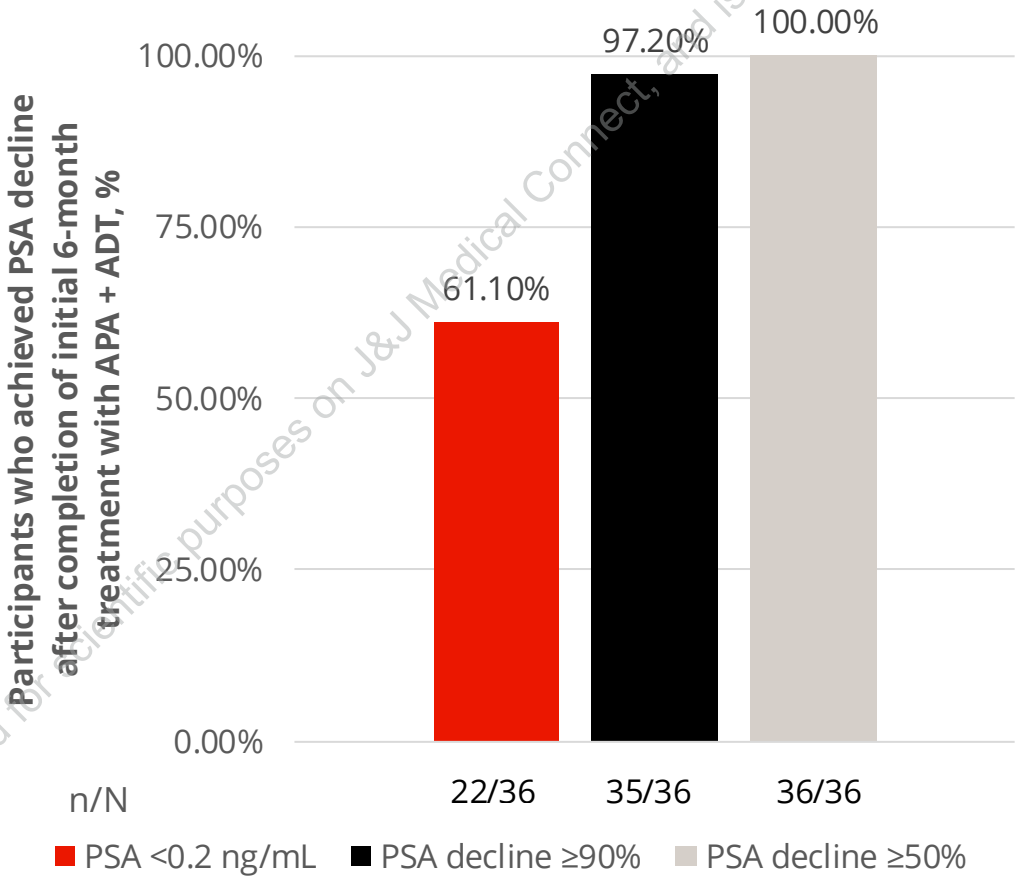

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Table 2: Confirmed PSA decline after 3 months of treatment with APA + ADT in participants during initial treatment phase

- PSA decline ≥ 50% and ≥90% from baseline and PSA < 0.2 ng/mL was achieved by 3 months of treatment by 100.0%, 94.4%, and 30.6% of participants, respectively.
- The median time to achieve PSA50 was 1.87 months, which was consistent for those reaching PSA90. For those achieving PSA0.2, the median time was slightly longer at 3.27 months.
- At 3 months, PSA50 and PSA90 responses in the Chinese subgroup were numerically better than those in the global population, while PSA0.2 was numerically inferior, possibly due to more severe baseline characteristics and significantly higher baseline PSA levels (Table 2).
- No new safety signals were observed in the Chinese subgroup.

Confirmed PSA decline	Enrolled participants N=36
PSA decline after 3 months, n (%)	
PSA decline ≥ 50%	36 (100.0%)
PSA decline ≥ 90%	34 (94.4%)
PSA < 0.2 ng/mL	11 (30.6%)
Median (range) time to achieve confirmed PSA decline, months	
PSA decline ≥ 50%	1.87 (1.8; 2.0)
PSA decline ≥ 90%	1.87 (1.8; 5.1)
PSA < 0.2 ng/mL	3.27 (2.7; 5.1)

PSA declines ≥50% and ≥90% are declines from baseline PSA level

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DISCLOSURES:

The authors declare no competing financial interest.

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