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Final results from PRESTO: A phase III open-label study of combined androgen blockade in patients (pts) with high-risk biochemically relapsed prostate cancer (BRPC) (AFT-19)

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Background

Prior analyses of PRESTO demonstrated that apalutamide (APA) prolonged PSA progression-free survival (PSA-PFS) without negatively impacting quality of life (QOL) in pts with high-risk BRPC. We report the results of extended follow-up including metastasis-free survival (MFS) and time to castration resistance (TTCR).

Methods

PRESTO is a randomized phase 3, open-label trial in pts with BRPC and PSA doubling time of ≤ 9 months (mo) without distant metastases on conventional imaging (NCT03009981). Pts were randomized 1:1:1 to receive a finite 52-week treatment course with androgen deprivation therapy (ADT), ADT + APA, or ADT + APA + abiraterone acetate with prednisone (AAP). After biochemical progression (PSA > 0.2 ng/mL), pts were treated per investigator discretion. MFS (by either conventional or metabolic imaging) was compared for each experimental arm vs control using Cox proportional hazard (CPH) (pre-planned) and 48-month restricted mean survival time (RMST) given the observed violation of the proportional hazard assumption. Other secondary endpoints included median TTCR and PSA-PFS in pts who recovered serum testosterone (T) to > 50 ng/dL. Median time to subsequent treatment (TTST) was analyzed in exploratory fashion.

Results

503 pts were randomized to ADT alone (N = 166), ADT + APA (N = 168) or ADT + APA + AAP (N = 169). With a median follow-up of 61 months and a total of 197 MFS events (39%) observed, the hazard ratio and 95% confidence interval (CI) for MFS and additional secondary and exploratory endpoint data are presented in the table. The difference in RMST over the first 48 months for MFS between ADT + APA vs ADT was 2.92 months (95% CI: 0.45 – 5.39) and for ADT + APA + AAP vs ADT was 2.41 months (95% CI: -0.20 – 4.62).Table: LBA88

Endpoint	Comparison	Hazard Ratio	95% CI
Metastasis-free survival	ADT + APA vs ADT	0.80	0.56 – 1.13
ADT + APA + AAP vs ADT	0.92	0.66 – 1.28	
Time to castration resistance	ADT + APA vs ADT	0.58	0.36 – 0.95
ADT + APA + AAP vs ADT	0.55	0.34 – 0.90	
Time to subsequent treatment	ADT + APA vs ADT	0.75	0.56 – 1.00
ADT + APA + AAP vs ADT	0.64	0.47 – 0.86	
PSA-PFS in the testosterone-recovered subset	ADT + APA vs ADT	0.71	0.55 – 0.93
ADT + APA + AAP vs ADT	0.61	0.47 – 0.80	

Conclusions

ADT plus APA, given for a finite duration of 52 weeks, prolongs MFS as assessed with 48-month RMST, in addition to lengthening TTCR and TTST in pts with high-risk BRPC.

Clinical trial identification

NCT03009981.

Legal entity responsible for the study

Alliance Foundation.

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Disclosure

All authors have declared no conflicts of interest.