EFFICACY AND SAFETY OF DAROLUTAMIDE PLUS ANDROGEN-DEPRIVATION THERAPY IN PATIENTS WITH METASTATIC HORMONE-SENSITIVE PROSTATE CANCER FROM THE PHASE 3 ARANOTE TRIAL

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DAROLUTAMIDE

INTRODUCTION

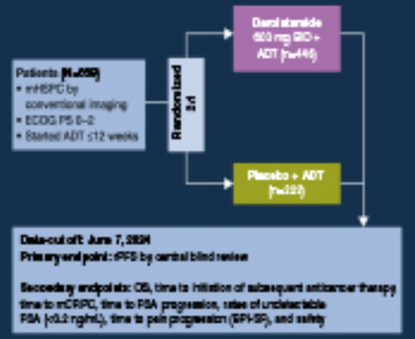
In the Phase 3 ARASENS study, darolutamide + ADT + docetaxel significantly improved overall survival versus placebo + ADT + docetaxel in patients with mHSPC[1]

OBJECTIVE

ARANOTE was designed to evaluate treatment without docetaxel (darolutamide + ADT versus ADT alone) to provide a new treatment option for mHSPC

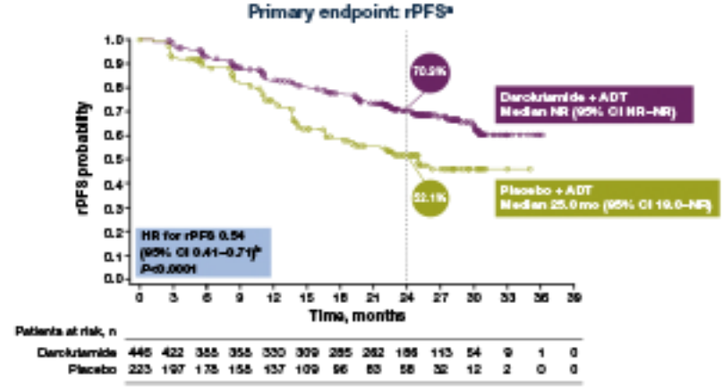
METHODS

Global, randomized, double-blind, placebo-controlled, Phase 3 study



ADT, androgen deprivation therapy; BID, twice a day; BPI-SF, Brief Pain Inventory (Short Form); ECOG PS, Eastern Cooperative Oncology Group Performance Status; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiologic progression-free survival.

Risk of radiologic progression or death reduced by 46% with darolutamide versus placebo



[a]Primary analysis occurred after 332 events (darolutamide 128; placebo 84); 46% and 85% OS were calculated using the Cox model stratified on visceral metastases (yes) and prior therapy (yes).
ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; NR, not reached; rPFS, radiologic progression-free survival.
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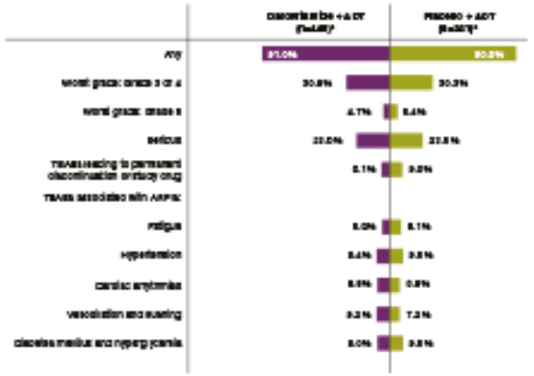
Incidence of treatment-emergent adverse events was similar between groups

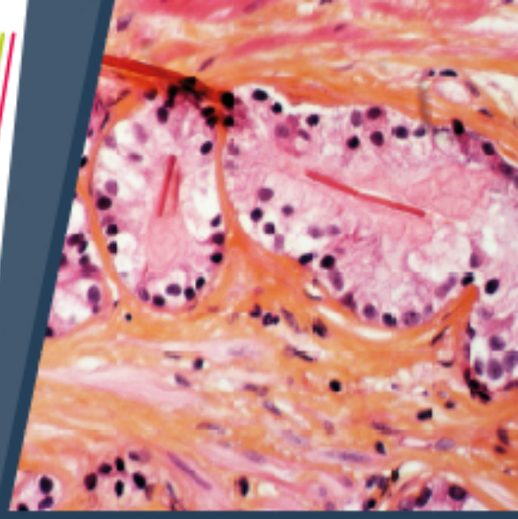


[a]Two patients who were randomized to the placebo group but received darolutamide are analyzed in the darolutamide group for the safety analysis.
ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; TEAE, treatment-emergent adverse event.

Darolutamide showed a benefit across all secondary endpoints

	Overall survival	Time to mCRPC	Time to PSA progression	Time to subsequent systemic therapy	Time to pain progression
Median, months (n/N; %)					
Darolutamide + ADT	NR (103/446; 23.1%)	NR (154/446; 34.5%)	NR (93/446; 20.9%)	NR (68/446; 15.2%)	NR (124/446; 27.8%)
versus	versus	versus	versus	versus	versus
Placebo + ADT	NR (60/223; 26.9%)	13.8 (143/223; 64.1%)	16.8 (108/223; 48.4%)	NR (74/223; 33.2%)	20.0 (79/223; 35.4%)
Stratified HR (95% CI)	0.81 (0.59–1.12)	0.40 (0.32–0.51)	0.31 (0.23–0.41)	0.40 (0.29–0.56)	0.72 (0.54–0.96)

[a]At the time of primary analysis, OS data are immature.
ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; mCRPC, metastatic castration-resistant prostate cancer; NR, not reached; OS, overall survival; PSA, prostate-specific antigen.



CONCLUSIONS

- Darolutamide + ADT significantly improved rPFS in patients with mHSPC
- Darolutamide showed a benefit across all secondary endpoints with a favorable safety profile
- Darolutamide + ADT without docetaxel should become an additional standard of care for mHSPC

SCAN ME FOR MORE INFO

Reference: 1. Smith MR, et al. N Engl J Med 2022;386:1132–42.

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