

Clinical outcomes based on PSA decline to undetectable PSA levels^a

	ENZA+ADT (n=507)		PBO+ADT (n=504)	
Subgroup, n (%)	Undetectable PSA (n=348 [68.6])	Detectable PSA (n=159 [31.4])	Undetectable PSA (n=89 [17.7])	Detectable PSA (n=415 [82.3])
Median OS, months (95% CI)	NR (54.21, NR)	36.4 (29.73, 48.46)	NR (50.33, NR)	47.7 (42.35, NR)
HR (95% CI)	0.24 (0.17, 0.34)		0.35 (0.22, 0.57)	
Median time to rPFS, months (95% CI)	NR (NR, NR)	14.00 (12.39, NR)	NR (NR, NR)	13.86 (12.35, 16.76)
HR (95% CI)	0.14 (0.09, 0.23)		0.24 (0.13, 0.43)	
Median time to PSA progression, months (95% CI)	NR (NR, NR)	NR (16.72, NR)	NR (NR, NR)	13.73 (11.07, 14.00)
HR (95% CI)	0.05 (0.02, 0.12)		0.07 (0.02, 0.17)	
Median time to new antineoplastic therapy, months (95% CI)	NR (NR, NR)	30.19 (20.04, 30.19)	NR (NR, NR)	21.06 (17.22, NR)
HR (95% CI)	0.13 (0.06, 0.26)		0.12 (0.05, 0.33)	
Median time to castration resistance, months (95% CI)	NR (NR, NR)	16.72 (13.83, NR)	NR (NR, NR)	11.01 (8.71, 11.20)
HR (95% CI)	0.16 (0.10, 0.25)		0.16 (0.09, 0.29)	

ORR, % (IQR) ^b	88.7 (80.6–94.2)	79.2 (68.0–87.8)	73.7 (48.8–90.9)	64.7 (56.6–72.3)
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^aThe number of patients who achieved undetectable PSA levels (<0.2 ng/mL); ^bThis analysis was conducted on patients who had measurable soft tissue disease at baseline (ENZA+ADT [undetectable PSA], n=97; ENZA+ADT [detectable PSA], n=72; PBO+ADT [undetectable PSA], n=19; PBO+ADT [detectable PSA], n=153).

ADT=androgen deprivation therapy; CI=confidence interval; ENZA=enzalutamide; HR=hazard ratio; IQR=interquartile range; NR=not reached; ORR=objective response rate; OS=overall survival; PBO=placebo; PSA=prostate-specific antigen; rPFS=radiographic progression-free survival.