

genitourinary tumours, prostate

762PD IMPACT OF ENZALUTAMIDE ON SKELETAL RELATED EVENTS (SRES), PAIN AND QUALITY OF LIFE (QOL) IN THE PREVAIL TRIAL

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Aim: Enzalutamide (ENZ) improved overall survival vs. placebo (PL) in PREVAIL, a phase 3 trial in asymptomatic/mildly symptomatic chemotherapy-naïve patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) [Beer et al, ASCO GU 2014]. PREVAIL also prospectively evaluated SREs, pain and QoL.

Methods: Pts were randomized to ENZ (160mg/day; n = 872) or PL (n = 845). SREs were assessed throughout the study and time to 1st SRE measured. QoL was assessed at baseline (BL) and during treatment (tx) on the FACT-P and EQ-5D; changes from BL over time were compared using repeated measures analyses. Pain was assessed with the BPI-SF at BL, and months (mo) 3 and 6. Pts with BL and ≥1 post-BL score were analyzed using pre-specified criteria for clinically meaningful pain progression (pain severity: increase ≥30% from BL; pain interference: increase ≥50% of BL standard deviation) and QoL deterioration (Cella et al, VIH 2009; Pickard et al, HQOL 2007).

Results: Median tx duration was 16.6 (ENZ) and 4.6 (PL) mo; BL pain and QoL scores were similar between arms. Overall, 32% (ENZ) and 37% (PL) of pts reported at least one SRE. Compared to PL, ENZ significantly reduces the risk of 1st SRE occurrence (hazard ratio: 0.72 [0.61, 0.84], p < 0.0001) and QoL deterioration (table). During the first 15 mo of tx, QoL as measured by FACT-P total scores and subscores was significantly better with ENZ (all p < 0.001 vs PL). ENZ significantly improved pain outcomes vs PL during the first 6 months of the tx (table).

Conclusions: In PREVAIL, in addition to overall survival benefit, ENZ was also associated with clinically significant patient benefits compared to PL, including a delay in time to 1st SRE, superior QoL, a delay in QoL deterioration, and significantly lower proportion of pts with pain.

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Table: 762PD

Time to 1st deterioration (mo), median (95% CI)				
	ENZ (n = 872)	PL (n = 845)	P-value	Hazard ratio ^a (95% CI)
EQ-5D instrument				
Visual analogue scale	22.14 (19.35;27.66)	13.83 (11.07;16.59)	<0.001b	0.67 (0.56;0.80)
FACT-P instrument				
Physical well-being	10.84 (8.31;11.07)	5.55 (5.49;5.62)	<0.001b	0.74 (0.65;0.85)
Functional well-being	8.54 (8.31;11.07)	3.09 (2.86;5.55)	<0.001b	0.72 (0.62;0.82)
Emotional well-being	19.48 (16.59;25.07)	11.01 (8.25;11.40)	<0.001b	0.67 (0.57;0.79)
Social well-being	24.87 (14.16;NYR)	8.51 (6.01;13.86)	<0.001b	0.74 (0.63;0.86)
Prostate Cancer Subscale	5.65 (5.55;8.31)	2.83 (2.79;2.96)	<0.001b	0.69 (0.60;0.78)
FACT-P total score	11.30 (11.07;13.86)	5.55 (5.49;5.59)	<0.001b	0.62 (0.54;0.72)
Pain progression, n(%)				
Pain severity	329/802 (41)	317/628 (50)	<0.001c	
Pain interference	247/788 (31)	255/613 (42)	<0.001c	