NEW DATA UPDATE

ERLEADA® + ADT: Long-term efficacy benefit vs. placebo + ADT in TITAN patients* with high and very high disease burden[1]

Erleada® (apalutamide) tablets

Background

- This *post-hoc* analysis of TITAN* evaluated the effectiveness and safety of ERLEADA® + ADT vs. placebo + ADT in an mHSPC patient population with heterogeneous, high-burden disease[1]

Methods

- Patients from TITAN* (N=1052) were classified into subgroups for analysis of clinical outcomes according to:[1]
  - **Number of baseline bone metastases:** <4, 4–<10, 10–<20 or ≥20
  - **Presence of lung metastases** (± other but not liver) at baseline
  - **Pain at baseline (BPI-SF score):** no/mild pain (0–3) or moderate/severe pain (≥4)
- Endpoints included OS, rPFS, PSA response, and safety†[1]

Prescribing information and adverse events reporting can be found on the back page.

ADT, androgen deprivation therapy; BPI-SF, Brief Pain Inventory-Short Form; CI, confidence interval; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; NR, not reached; OS, overall survival; rPFS, radiographic progression-free survival; PFS2, second progression-free survival; PSA, prostate-specific antigen.

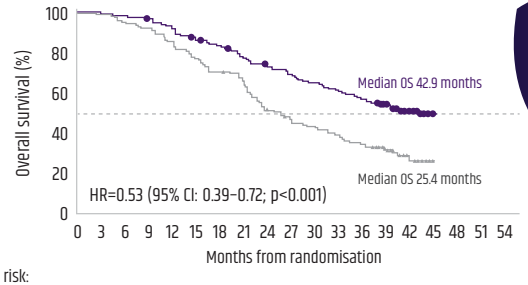
*TITAN is a double-blind, randomised, placebo-controlled international Phase III study evaluating ERLEADA® + ADT vs. placebo + ADT in patients with mHSPC (N=1052; ERLEADA® + ADT [n=525], placebo + ADT [n=527]).[2] Dual primary endpoints of the TITAN study were rPFS and OS. rPFS was estimated as the time from randomisation to first imaging-based documentation of disease progression or death, whichever occurred first.[2,3] Median follow-up of 44 months in the final analysis.[3]

†Endpoints were assessed using descriptive statistics, the Kaplan–Meier method, and the Cox proportional-hazards model.[1] rPFS was assessed at 22.7 months median follow-up (first interim analysis); all other clinical endpoints were assessed at 44.0 months median follow-up (final analysis).[1]

Results

*"Our results indicate that **patients with a high number of bone metastases, lung metastases, or pain at presentation can derive benefit from doublet therapy with apalutamide** due to its favourable safety profile, while **avoiding docetaxel-related toxicities**"*[1]

OS in patients with **≥20 bone metastases** at baseline†[1]

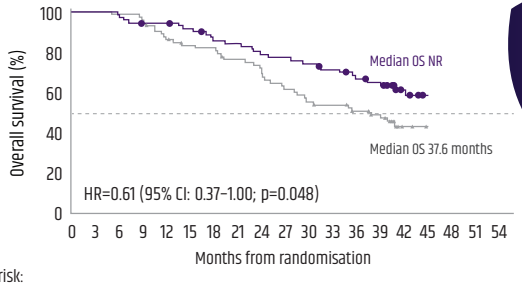


47% reduction in the risk of death with ERLEADA® + ADT vs. placebo + ADT[1]

No. at risk:

ERLEADA® + ADT	146	144	142	139	132	123	117	108	101	95	90	84	79	66	43	26
Placebo + ADT	138	137	129	126	112	105	96	86	68	58	55	49	45	32	19	6

OS in patients with **10–<20 bone metastases** at baseline†[1]



39% reduction in the risk of death with ERLEADA® + ADT vs. placebo + ADT[1]

No. at risk:

ERLEADA® + ADT	72	72	70	67	67	64	59	58	54	53	51	48	44	40	23	15
Placebo + ADT	74	74	129	71	62	58	57	52	46	42	38	36	32	27	13	10

Efficacy outcomes according to **pain at baseline**†[1]

Outcomes	BPI-SF score	Events/n		Median, months		HR (95% CI)	p-value
		ERLEADA® + ADT	Placebo + ADT	ERLEADA® + ADT	Placebo + ADT		
OS	0–3	124/392	178/407	NR	52.2	0.65 (0.51–0.81)	<0.001
	≥4	39/110	52/106	NR	43.9	0.66 (0.43–0.998)	0.049
rPFS	0–3	102/392	175/407	NR	25.6	0.50 (0.40–0.65)	<0.001
	≥4	30/110	50/106	28.7	18.5	0.52 (0.33–0.83)	0.006
Time to castration resistance	0–3	135/392	287/407	NR	12.9	0.32 (0.26–0.40)	<0.001
	≥4	50/110	79/106	NR	9.2	0.45 (0.32–0.65)	<0.001
Time to PSA progression	0–3	98/392	266/407	NR	14.6	0.25 (0.20–0.32)	<0.001
	≥4	35/110	70/106	NR	10.1	0.35 (0.23–0.52)	<0.001
PFS2	0–3	127/392	187/407	NR	44.5	0.62 (0.49–0.77)	<0.001
	≥4	39/110	54/106	NR	38.8	0.61 (0.4–0.92)	0.017

Regardless of pain at baseline, **significant benefits across all efficacy outcomes** with ERLEADA® + ADT vs. placebo + ADT[1]

Figures adapted from Rodriguez-Vida A, *et al.* 2025[1]

ERLEADA® + ADT was generally well tolerated in patients with high disease burden, and no new safety signals were observed across subgroups[1]

*"These findings provide **strong evidence in favour of early intensification with apalutamide in patients with mHSPC and features of more aggressive and symptomatic disease**"*[1]

Click here to access the original publication

PUSH BACK EARLY.
EXTEND LIFE.[2–4]

Erleada® (apalutamide) tablets

Operating companies to insert relevant localised PI as per local requirements

Abbreviated ERLEADA® Prescribing Information

ERLEADA® is indicated:[4]

- in adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease
- in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT)

References:

1. Rodriguez-Vida A, *et al. Eur Urol Oncol* 2025 [in press]. **2.** Chi KN, *et al. N Engl J Med* 2019;381:13–24. **3.** Chi KN, *et al. J Clin Oncol* 2021;39:2294–2303. **4.** ERLEADA®. Summary of Product Characteristics (Nov 2024). Janssen-Cilag International NV. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/erleada. Accessed: October 2025.

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