TREAT EARLY WITH ERLEADA™ + ADT

for robust and long-term benefits in your mHSPC patients, including those with synchronous/high-volume disease[1]

Erleada™ (apalutamide) tablets

Give your patients with mHSPC the opportunity to experience the established benefits of ERLEADA™ + ADT, regardless of tumour burden and timing of metastasis, including your patients with synchronous/ high-volume disease[1]

▼ This medicinal product is subject to additional monitoring. This will allow quick identication of new safety information. Healthcare professionals are asked to report any suspected Adverse reactions. See undesireable events section of the Summary of Product Characteristics for how to report adverse reaction.

ERLEADA™ is indicated:[2]

- 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)

ADT, androgen deprivation therapy; mHSPC, metastatic hormone-sensitive prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer.

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Meet Abdullah,* a proud taxi driver

Erleada™ (apalutamide) tablets

Abdullah clinical characteristics*[3–6]

Age: 63[3]

History: No previous history of prostate cancer[3,4]

Current diagnosis: *De novo* mHSPC[3,4]

Disease volume:† High – lung metastases;‡ 8 bone metastases on bone scan[5]

PSA: 124 ng/mL[3]

Gleason score: 8 (4+4)[3]

Comorbidities: Hypertension, mild renal insufficiency and hypercholesterolaemia§¶[2,6]

Prognosis: Life expectancy of around 4 years[7]

How can ERLEADA™ + ADT help patients like Abdullah who may only have 4 years of life ahead?*[7]

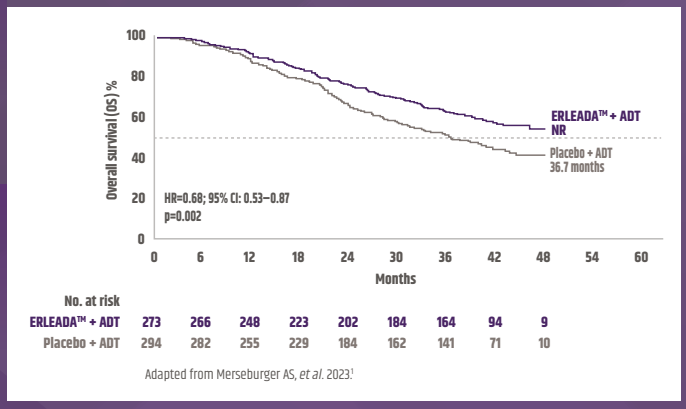
Patients with **synchronous mHSPC** generally have a **poor prognosis**[8,9]

ERLEADA™ + ADT significantly prolonged overall survival (OS) vs. placebo + ADT[1,4]

35% reduction in risk of death vs. placebo + ADT in the overall TITAN‖ study population[4]
HR (95% CI): 0.65 (0.53–0.79); p<0.0001[4]

32% reduction in risk of death in the synchronous/high-volume TITAN study sub-population[1]
HR (95% CI): 0.68 0.53–0.87); p=0.002[1]

Figure 1: Overall survival in synchronous/high-volume mHSPC patients
(median follow-up of 44 months)[1]



Adapted from Merseburger AS, *et al.* 2023.[1]

ERLEADA™ + ADT significantly delayed time to castration resistance vs. placebo + ADT[1,4]

66% reduction in the risk of castration resistance in the overall TITAN‖ study population[4]
HR=0.34; 95% CI: (0.29–0.41); p< 0.0001[4]

60% reduction in the risk of castration resistance in patients with synchronous/high-volume disease[1]
HR=0.40; 95% CI: (0.32–0.50); p<0.001[1]

ERLEADA™ + ADT delays time to castration resistance by **30.5 months** in patients with synchronous/high-volume disease vs. placebo + ADT[1]

ERLEADA™ + ADT is recommended for all mHSPC patient sub-populations, across European and US guidelines[10–12]

ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; NR, not reached; OS, overall survival; PSA, prostate-specific antigen.

*Fictional patient based on the clinical characteristics of mHSPC patients included in the TITAN study.[3–6]

†In TITAN, high-volume disease was defined as visceral metastases and ≥1 bone lesion or ≥4 bone lesions with ≥1 outside of the vertebral column/pelvis. Low-volume disease was defined as the presence of bone lesions not meeting high-volume definition.[6]

‡No dose adjustment is necessary for patients with baseline mild or moderate hepatic impairment. ERLEADA™ is not recommended in patients with severe hepatic impairment as there are no data in this patient population and apalutamide is primarily hepatically eliminated.[2]

§If ERLEADA™ is prescribed, patients with clinically significant cardiovascular disease should be monitored for risk factors such as hypercholesterolaemia, hypertriglyceridaemia, or other cardio-metabolic disorders.[2]

¶No dose adjustment is necessary for patients with mild to moderate renal impairment. Caution is required in patients with severe renal impairment as ERLEADA™ has not been studied in this patient population.[2]

‖TITAN is a double-blind, randomised, placebo-controlled international Phase III study evaluating ERLEADA™ + ADT vs placebo + ADT in patients with mHSPC (N=1052).[6]

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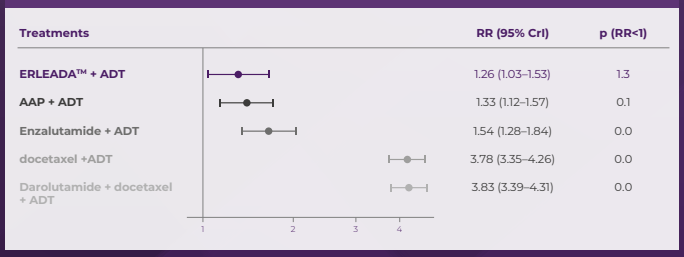
ERLEADA™ + ADT offers an established and manageable safety profile in mHSPC patients while maintaining their QoL[1,2,4,6]

Incidence of any TEAEs were similar in the overall TITAN patient population treated with ERLEADA™ + ADT vs placebo + ADT.[4] Cumulative incidence of grade 3–4 and serious TEAEs were **similar** in ERLEADA™ + ADT and placebo + ADT **regardless of disease volume or metastatic presentation at diagnosis[1]**

A network meta-analysis on the safety of systemic treatments in mHSPC revealed:[14]

- **ERLEADA™ + ADT ranked better than the docetaxel-based regimens** in safety analyses for grade ≥3 AEs, sAEs, and any AEs[14]
- ERLEADA™ + ADT had the **lowest relative risk of grade ≥3 AEs, sAEs** (Figure 2) **and any AEs compared with other doublet and triplet regimens[14]**

Figure 2: Relative risk for aggregated outcomes for sAEs following systemic therapies vs. ADT alone[14]



Adapted from DiMaio M, *et al.* 2023.[14]

ERLEADA™ + ADT maintained HRQoL in patients with mHSPC with no substantial differences vs. placebo + ADT,[4] offering minimal burden for patients like Abdullah during treatment

The STAMPEDE trial† showed that docetaxel + ADT was associated with initial declines in HRQoL outcomes from baseline, suggesting that regimens including docetaxel may negatively impact patients' HRQoL[13]

2 years

The impact on patients' QoL in the STAMPEDE trial was observed for 2 years post randomisation to docetaxel/abiraterone + ADT[13]

At 44 months' median follow-up:

1.5× as many patients like Abdullah* with synchronous/high-volume mHSPC, remained on treatment with ERLEADA™ + ADT vs. placebo + ADT[1]

44% vs. 28% of patients on ERLEADA™ + ADT vs. placebo + ADT continued treatment‡[1]

Choose ERLEADA™ early for your mHSPC patients, including those with synchronous/high-volume disease like Abdullah* for robust, long-term outcomes and manageable safety profile[1]

AAP, abiraterone acetate and prednisolone; ADT, androgen deprivation therapy; AE, adverse event; CrI, credible interval; mHSPC, metastatic hormone-sensitive prostate cancer; NHT, novel hormonal therapy; QoL, quality of life; RR, relative risk; sAE, serious adverse event.

*Fictional patient based on the clinical characteristics of mHSPC patients included in the TITAN study.[3–6]

†A group of patients with high-risk locally advanced or mHSPC within the randomised controlled STAMPEDE trial were contemporaneously enrolled to compare QoL outcomes with abiraterone acetate + prednisone or prednisolone + ADT (n=342) vs. docetaxel + ADT (n=173).[13]

‡43.9% (n=120/273) vs. 27.9% (n=82/294) of patients with synchronous/high-volume mHSPC continued treatment with ERLEADA™ + ADF vs. placebo + ADT.[1]

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Scan the QR Code for Erleada™ Prescribing Information

References
1. Merseburger AS, *et al. Eur J Can* 2023;193:113290. **2.** ERLEADA™. Summary of Product Characteristics (September 2023). Janssen-Cilag International NV. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/erleada. Accessed: November 2023. **3.** Chi KN, *et al. J Clin Oncol* 2021;39:2294–2303 (supplementary). **4.** Chi KN, *et al. J Clin Oncol* 2021;39:2294–2303. **5.** Chi KN, *et al. N Engl J Med* 2019;381:13–24 (supplementary).
6. Chi KN, *et al. N Engl J Med* 2019;381:13–24. **7.** Ng K, *et al. Oncol Ther.* 2020;8:209–230. **8.** Francini E, *et al. Prostate* 2018;78:889–895. **9.** Oing C, Bristow RG. *ESMO Open.* 2023;8:101194. **10.** Mottet N, *et al.* EAU Guidelines. Edn. Presented at the EAU Annual Congress Milan 2023. **11.** Virgo KS, *et al.* Oral presentation at the ASCO Annual Meeting, June 2–6, 2023. **12.** Parker C, *et al.* ESMO Guidelines. *Ann Oncol.* 2020;31:1119–1134. **13.** Rush HL, *et al.*
J Clin Oncol 2022;40(8):825–836. **14.** DiMaio D, *et al.* European Multidisciplinary Congress on Urological Cancers 2023. 02–05 November. Poster: P107.

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