Erleada™ (apalutamide) tablets ▼

ERLEADA™ + ADT TAKES ULTRA-LOW PSA RESPONSES IN mHSPC TO A NEW LOW WITH A FAVOURABLE SAFETY PROFILE[1,2]

Explore key updates on ERLEADA™ + ADT outcomes in patients with mHSPC, presented at ESMO 2023 and EMUC 2023 congresses

▼ 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.

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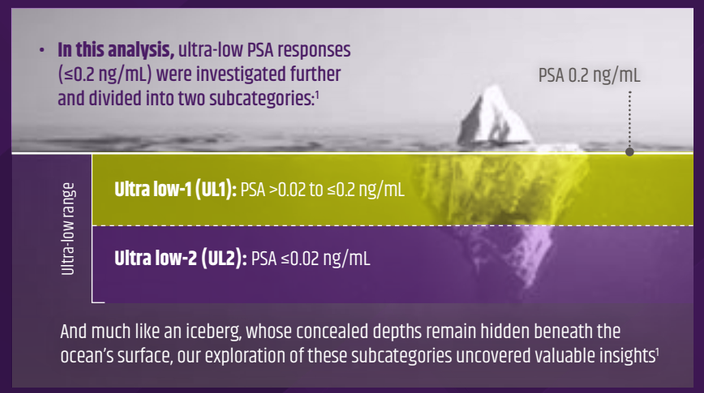
ERLEADA™ + ADT takes ultra-low PSA responses in mHSPC to a new low[1]

ESMO 2023 UPDATE

BACKGROUND & METHODS:

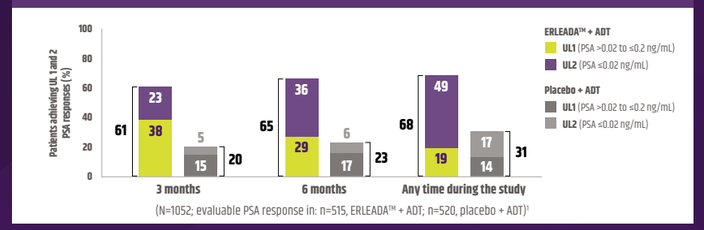
- Patients with mHSPC on ERLEADA™ + ADT achieved a rapid and deep PSA response, which correlates with improved survival[2,3]
- **ERLEADA™ is the first approved NHT to report the impact of previously unexplored ultra-low PSA (<0.2 ng/mL) concept and responses** on clinical outcomes in patients with mHSPC, as assessed in this *post hoc* analysis of TITAN*[1,4–10]



RESULTS:[1]

- **More than twice as many patients on ERLEADA™ + ADT achieved a UL1 or 2 PSA response** at any point during the study vs. placebo + ADT (Figure 1)

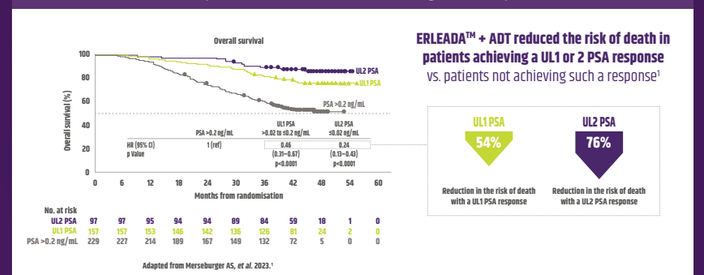
Figure 1: Patients achieving UL1 and 2 PSA responses over time[1]



(N=1052; evaluable PSA response in: n=515, ERLEADA™ + ADT; n=520, placebo + ADT)[1]

- Regardless of disease volume at baseline, **achieving a UL1 or 2 PSA response at 3 months** vs. not achieving such a response **improved clinical outcomes,** including:
  - OS (Figure 2)
  - rPFS
  - Time to castration resistance
  - Time to PSA progression
- **The clinical benefits of ERLEADA™ + ADT were more pronounced in patients achieving a UL2 PSA response** vs. not achieving such a response

Figure 2: ERLEADA™ + ADT improved OS in patients achieving a UL1 or 2 PSA response at 3 months vs. not achieving such a response[1]



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

CONCLUSION:

More than twice as many patients with mHSPC on ERLEADA™ + ADT achieved a UL1 or 2 PSA response vs. placebo + ADT, which was associated with improved clinical outcomes vs. not achieving a response, including reduction in the risk of death (54% for UL1 and 76% for UL2)† – regardless of disease volume at baseline[1]

For more information, visit the original poster

ERLEADA™ + ADT offers improved survival in mHSC with a favourable safety profile[11,12]

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EMUC 2023 UPDATE

RESULTS:

Findings confirmed that achieving UL PSA levels with ERLEADA™ + ADT is associated with improved OS in mHSPC patients[11]

- This association appears to be more pronounced with ERLEADA™ + ADT vs. triplet therapy (ADT + NHT + chemotherapy, Table 1)[11]

CONCLUSION:

Achieving UL PSA levels is associated with improved survival outcomes in mHSPC patients[11]

Table 1: HR for OS of PSA-responders (≤0.2ng/mL) vs non-responders (>0.2ng/mL)[11]

Treatments[1]	HR (95% CI)	p-value
Best response		
ERLEADA™ + ADT	**0.17 (0.13–0.23)**	**<0.001**
Enzalutamide + ADT	0.24 (0.17–0.34)	<0.001
24 weeks landmark		
ERLEADA™ + ADT	**0.20 (0.14–0.20)**	**<0.001**
Darolutamide + docetaxel + ADT	0.47 (0.35–0.63)	<0.001
36 week landmark		
ERLEADA™ + ADT	**0.18 (0.12–0.26)**	**<0.001**
Darolutamide + docetaxel + ADT	0.37 (0.28–0.49)	<0.001
7 months landmark		
ERLEADA™ + ADT	**0.18 (0.12–0.27)**	**<0.001**
Docetaxel + ADT	0.62 (0.49–0.78)	<0.001

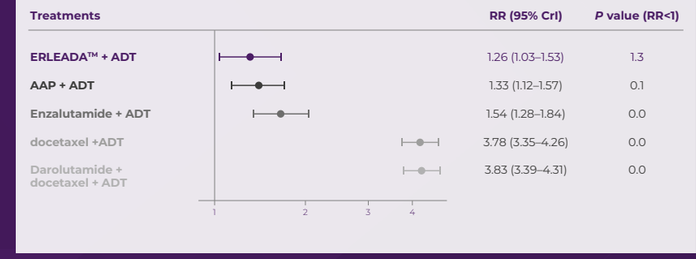
Adapted from Puente J, *et al*. 2023.[11]

RESULTS:

A network meta-analysis on the safety of systemic treatments in mHSPC revealed:[12]

- ERLEADA™ + ADT ranked better than the docetaxel-based doublet and triplet regimens in safety anaylses for grade ≥3 AEs, sAEs, and any AEs
- Compared to ADT alone, ERLEADA™ + ADT had the lowest relative risk of grade ≥3 AEs, sAEs (Figure 3) and any AEs

Figure 3: Relative risk for SAEs vs ADT alone.[12]



Adapted from DiMaio D, *et al*. 2023.[2]

CONCLUSION:

ERLEADA™ + ADT demonstrated a favourable safety profile compared with docetaxel-based regimens with lowest relative risk of grade ≥3 AEs, sEAs and any AEs[12]

For more information, visit the original posters

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PUSH BACK EARLY.
EXTEND LIFE.[13–15]

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ERLEADA™ + ADT has a manageable safety profile in mHSPC at a median follow-up of nearly 4 years.[14]

ERLEADA™ is indicated:[15]

- 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)

Scan the QR Code for Erleada™ Prescribing Information

AAP, abiraterone acetate and prednisolone; ADT, androgen deprivation therapy; AE, adverse event; CI, confidence interval; CrI, credible interval; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; NHT, novel hormonal therapy; nmCRPC, non-metastatic castration-resistant prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival; sAE, serious adverse event; UL, ultra-low. *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]).[11] Evaluable PSA responses in this analysis included 515 patients on ERLEADA™ + ADT and 520 patients on placebo + ADT.[1] Clinical outcomes included OS, rPFS, time to castration resistance, and time to PSA progression and were evaluated using landmark analysis at 3 and 6 months, Kaplan–Meier method, and Cox proportional hazards model. Median follow-up was 22.7 months for rPFS, and 44 months for OS, time to PSA progression, and time to castration resistance.[1]
†Compared with not achieving a UL1 or 2 PSA response, achieving a response in mHSPC reduced the risk of death by 54% with a UL1 response (HR=0.46; 95% CI: 0.31–0.76; p<0.0001), and by 76% with a UL2 PSA response (HR=0.24; 95% CI: 0.13–0.43; p<0.0001).[1]

References
1. Merseburger AS, *et al.* European Society for Medical Oncology 2023. 20–24 October. Poster: 1786. **2.** Chowdhury S, *et al. Ann Oncol* 2023;27:S0923–7534(23)00086-8. **3.** Naqvi S, *et al.* American Society of Clinical Oncology (ASCO) Genitourinary Cancers 2023. 16–18 February. Poster: 195. **4.** Smith MR, *et al. N Eng J Med* 2022;386:1132–1142. **5.** Fizazi K, *et al. N Eng J Med* 2017;377:352–360. **6.** Armstrong AJ, *et al. J Clin Oncol* 2019;37(32):2974–2986. **7.** Petrylak, *et al.* European Society of Medical Oncology Congress 2022. 9–13 September. Poster: 1398. **8.** Matsubara N, *et al. Eur Urol* 2020;77(4):494–500. **9.** Saad F, *et al.* American Urological Association Annual Meeting 2023. 28 April–1 May. Abstract MP29. **10.** Gravis G, *et al.* European Society for Medical Oncology Congress 2022. 9–13 September. Oral presentation. **11.** Puente J, *et al.* European Multidisciplinary Congress on Urological Cancers 2023. 2–5 November. Poster: 105. **12.** DiMaio D, *et al.* European Multidisciplinary Congress on Urological Cancers 2023. 2–5 November. Poster: P107. **13.** Chi KN, *et al. J Clin Oncol* 2021;39:2294–2303. **14.** Chi KN, *et al. N Engl J Med* 2019;381:13–24. **15.** ERLEADA™. Summary of Product Characteristics (September 2023). Janssen-Cilag International NV. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/erleada. Accessed: October 2023.

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