janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Push back early
Extend life.[1–4]

Real-world clinical outcomes in mHSPC favour first-line ERLEADA® + ADT
vs. other approved NHT regimens*[5–9]

*Approved NHT regimens include enzalutamide and abiraterone acetate.[10,11]

ERLEADA® is indicated:[1]

- 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)

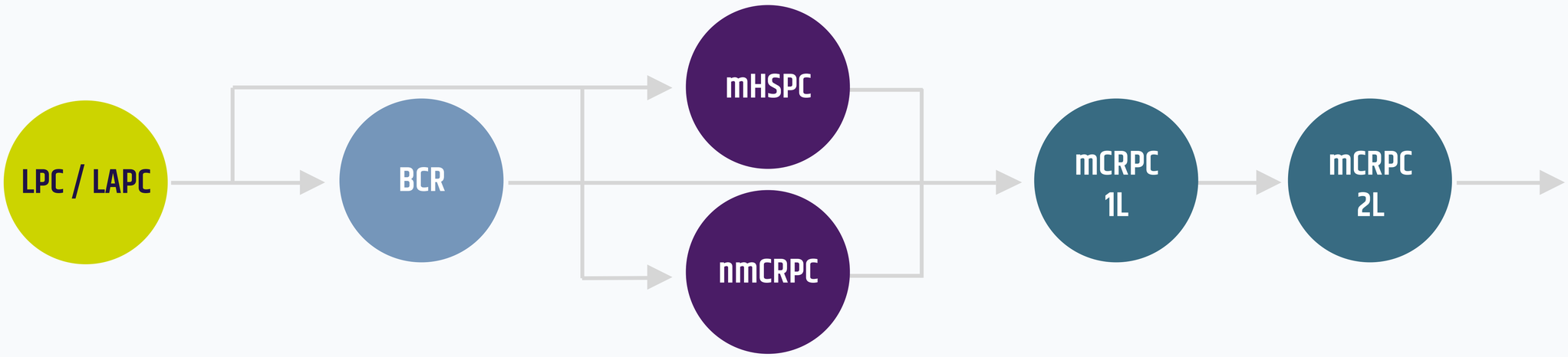
Full Prescribing information, adverse events reporting, and references can be found through accessing the buttons at the top right-hand corner of each page.

CP-444961 | Date of preparation: March 2024

In the complex realm of prostate cancer care, choosing the right treatment for each patient can pose a great challenge[12]

Metastasis and CR can reduce patients' OS, requiring early intervention to delay progression[13]

Prostate cancer clinical states model[14,15]



Localised disease: Curative intent | **Advanced disease:** Extending stage | **Late disease:** Extending survival

Adapted from Scher HI, *et al.* 201614 and Mottet N, *et al.* 2022.[15]

- Upfront use of ERLEADA® + ADT in mHSPC **ensures patients don't miss their chance to receive ERLEADA® + ADT** [1,10,11,16,17]
- Upon progression to mCRPC**, this treatment option is lost** [1,10,11,16,17]

ERLEADA® + ADT is Recommended by EAU and ESMO for 1L treatment of mHSPC[15,18]

Erleada® (apalutamide) tablets

First-line ERLEADA® + ADT provides ~6 years predicted median OS[4]

ERLEADA® + ADT offers superior median predicted OS for mHSPC patients

vs. placebo + ADT, regardless of disease volume*[4]

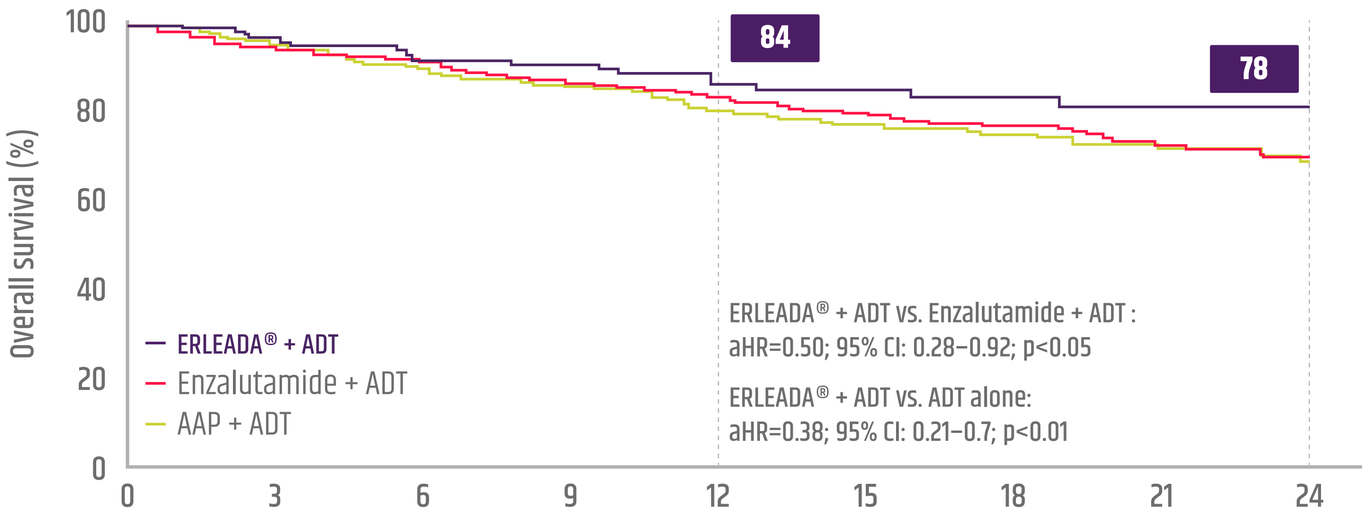
Overall population:	High-volume mHSPC:	Low-volume mHSPC:
ERLEADA® + ADT	ERLEADA® + ADT	ERLEADA® + ADT
~6 years (71.5 months) predicted median OS (vs. 39.5 months with placebo + ADT)[4]	**4.3 years** (51.9 months) predicted median OS (vs. 33.8 months with placebo + ADT)[4]	**9.4 years** (113.1 months) predicted median OS (vs. 47.3 months with placebo + ADT)[4]

*Data from a statistical extrapolation study conducted to predict median OS beyond the original follow-up period in the TITAN study, where median OS was not reached in the ERLEADA® + ADT arm in the final analysis. The study predicted median OS for the overall population, with and without weighting adjustments; subgroups were analysed based on disease volume and timing. Patient-level data were fitted to six models, and the best fit was determined using statistical and visual criteria.[4]

First-line ERLEADA® + ADT prolongs OS in mHSPC patients vs. other approved NHTs*[5]

In the real-world setting,† first-line ERLEADA® + ADT provided significantly longer OS vs. either enzalutamide + ADT or abiraterone acetate[5]

Overall survival (%)[5]



No. at risk									
ERLEADA® + ADT (N=165)	**144**	**132**	**107**	**85**	**63**	**51**	**37**	**23**	**12**
Enzalutamide + ADT (N=643)	394	342	283	225	169	120	93	56	35
AAP + ADT (N=1064)	555	490	429	351	270	206	153	102	70

Adapted from Maughan BL, *et al*. 2024.[20]

ERLEADA® + ADT

50%

reduced risk of death vs. enzalutamide + ADT (p<0.05)

ERLEADA® + ADT

49%

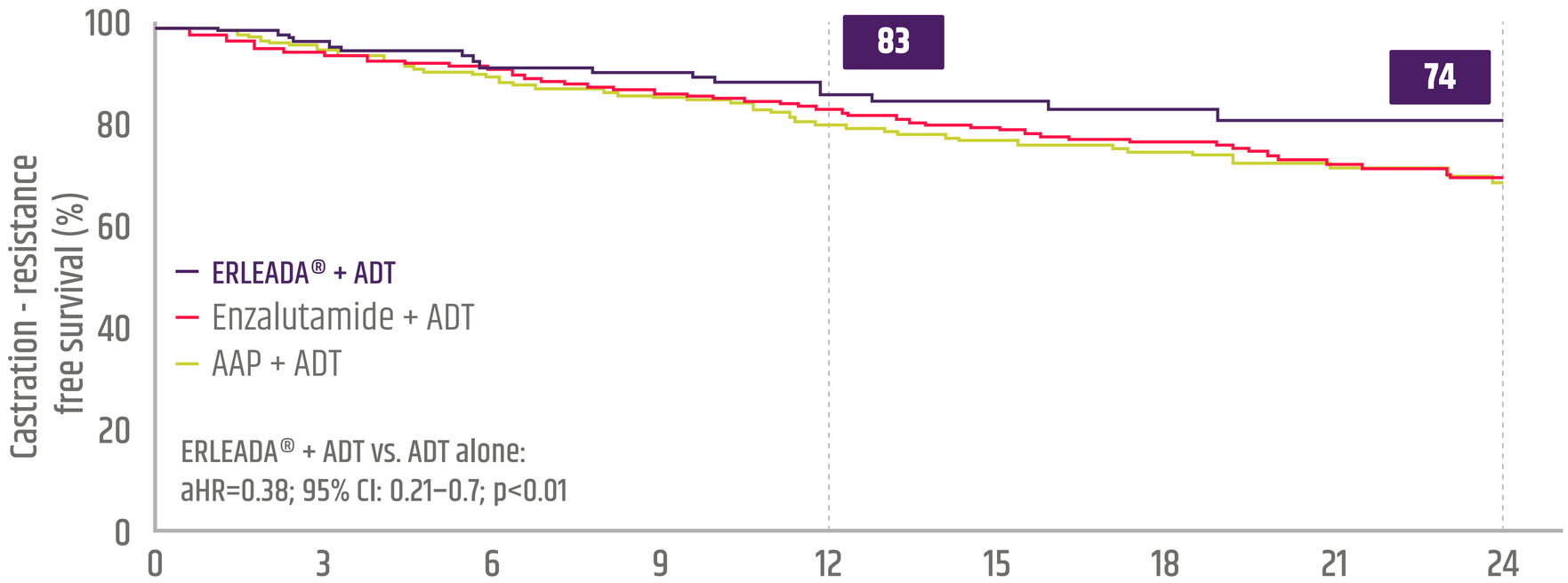
reduced risk of death vs. AAP + ADT (p<0.05)

*Approved NHT regimens include enzalutamide and abiraterone acetate.10,11 †Data from a retrospective, observational cohort study which examined the impact of approved NHT treatment regimens (ERLEADA®, enzalutamide, or AAP) + ADT and ADT alone as first-line therapy in mHSPC on short- and long-term clinical outcomes in real-world clinical practice in the United Stated (N=4626). Kaplan–Meier method was used to estimate OS, PSA reduction, and CR rates. aHR of risk of death was estimated using Inverse Probability of Treatment Weighted multivariate Cox proportional hazard models adjusted for age, comorbidities, BMI, and baseline PSA.[5]

First-line ERLEADA® + ADT delays TTCR in mHSPC patients vs. other approved NHTs*[5]

In the real-world setting,† ERLEADA® + ADT prolonged TTCR vs. either enzalutamide + ADT or AAP + ADT[5]

Time to castration resistance (%)[5]



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ERLEADA® delivers more rapid and deeper PSA responses in patients with mHSPC vs. other approved NHTs*[8,9]

In the real-world setting,† a higher proportion of patients with mHSPC on ERLEADA® achieved PSA90 responses overall during the 12 month observation period vs. either enzalutamide or abiraterone acetate‡[8,9]

ERLEADA® reduces the median time to PSA90 vs. other approved NHTs*[8,9]

View data

More patients on ERLEADA® achieve PSA90 responses vs. other approved NHTs*[8,9]

View data

*Approved NHT regimens include enzalutamide and abiraterone acetate.[10,11] †Data are from electronic medical records from PPS Analytics including data from US community urology practices linked with administrative claims from the Komodo Health Solutions Research Database; PSA90 was defined as the earliest attainment of ≥90% decline in PSA relative to pre-index (most recent value within 13 weeks). Patients were followed from index date to earliest of index regimen discontinuation, treatment switch, end of clinical activity or end of data availability.[8,9] ‡Concurrent prednisone use was not required for inclusion in the abiraterone acetate cohort.[9]

ERLEADA® delivers more rapid and deeper PSA responses in patients with mHSPC vs. other approved NHTs*[8,9]

Median time to PSA90 in the real-world setting (months)†‡[8,9]

ERLEADA®

3.7 Months[8]

Enzalutamide

5.1 Months[8]

1.4 months faster

ERLEADA®

3.6 Months[9]

Abiraterone acetate

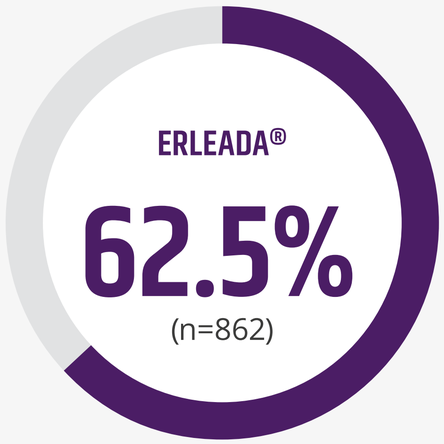
10.3 Months[9]

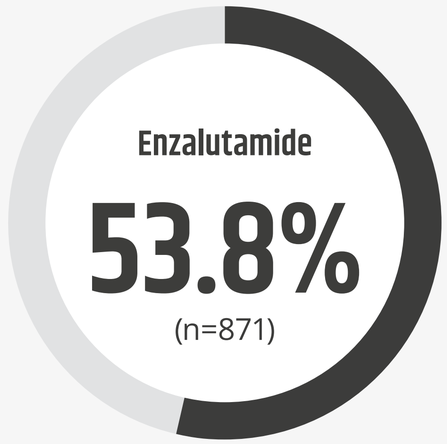
6.7 months faster

*Approved NHT regimens include enzalutamide and abiraterone acetate.[10,11] †Data are from electronic medical records from PPS Analytics including data from US community urology practices linked with administrative claims from the Komodo Health Solutions Research Database; PSA90 was defined as the earliest attainment of ≥90% decline in PSA relative to pre-index (most recent value within 13 weeks). Patients were followed from index date to earliest of index regimen discontinuation, treatment switch, end of clinical activity or end of data availability.[8,9] ‡Concurrent prednisone use was not required for inclusion in the abiraterone acetate cohort.[9]

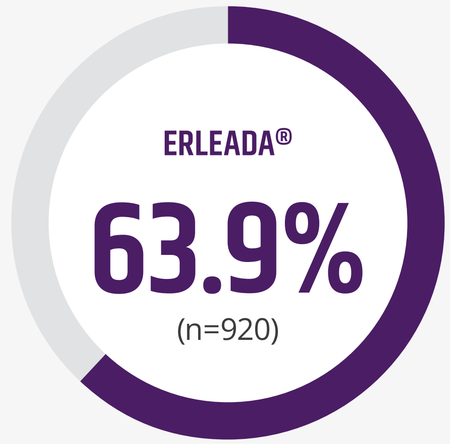
ERLEADA® delivers more rapid and deeper PSA responses in patients with mHSPC vs. other approved NHTs*[8,9]

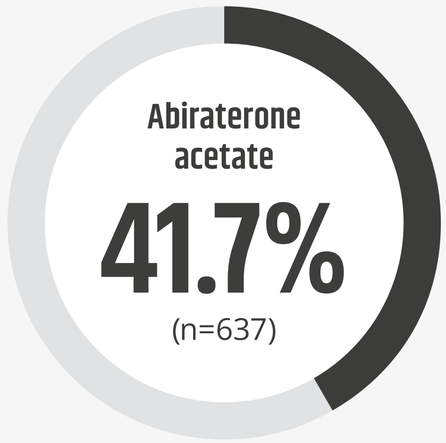
Proportion of patients achieving PSA90 at 6 months in the real-world setting (%)†‡[8,9]





HR=1.21; 95% CI: 1.05–1.40; p=0.008[8]





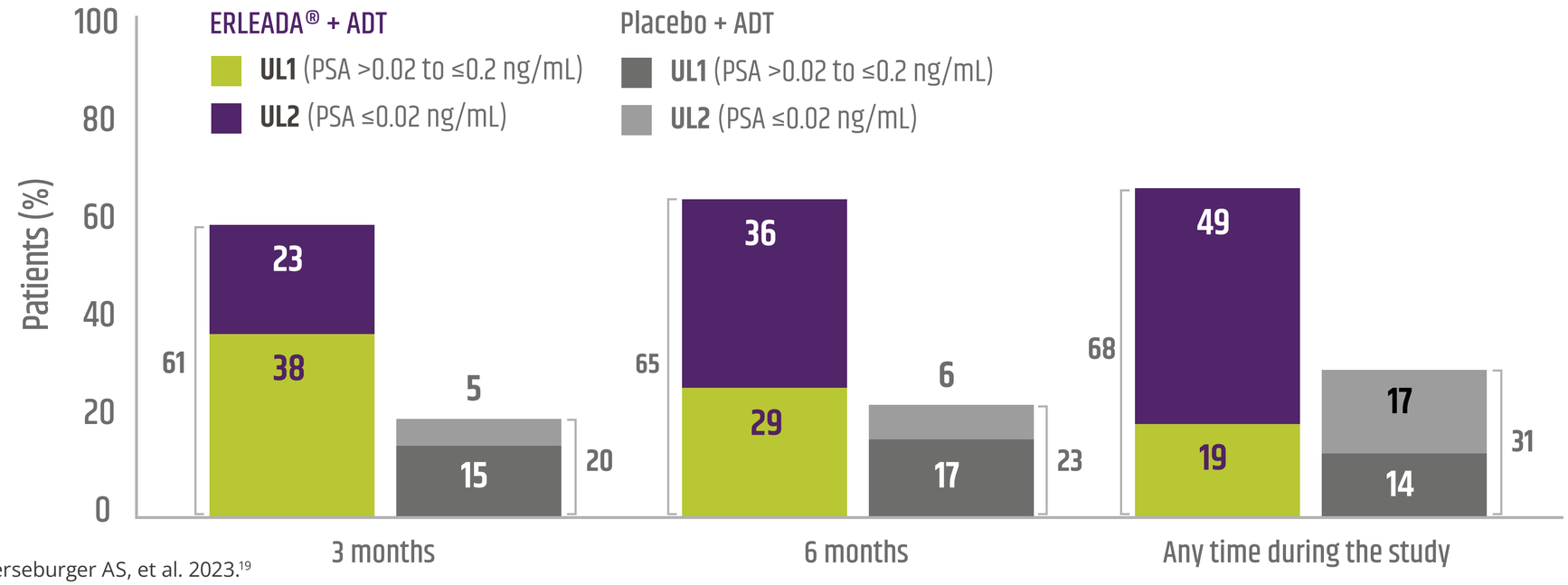
HR=1.68; 95% CI: 1.42–2.40; p<0.001[9]

*Approved NHT regimens include enzalutamide and abiraterone acetate.[10,11] †Data are from electronic medical records from PPS Analytics including data from US community urology practices linked with administrative claims from the Komodo Health Solutions Research Database; PSA90 was defined as the earliest attainment of ≥90% decline in PSA relative to pre-index (most recent value within 13 weeks). Patients were followed from index date to earliest of index regimen discontinuation, treatment switch, end of clinical activity or end of data availability.[8,9] ‡Concurrent prednisone use was not required for inclusion in the abiraterone acetate cohort.[9]

ERLEADA® + ADT takes undetectable PSA responses in mHSPC to a new low[19]

≥2X more patients achieved undetectable (UL 1 [PSA >0.02 to ≤0.2 ng/mL] **and UL 2** [PSA ≤0.02 ng/mL]**)**
PSA responses on ERLEADA® + ADT at 3 months vs. placebo + ADT**, which is associated with improved OS**
vs. not achieving a response*[19]

Patients achieving undetectable (UL1 and 2) PSA responses over time (%)[19]



Adapted from Merseburger AS, et al. 2023.[19]

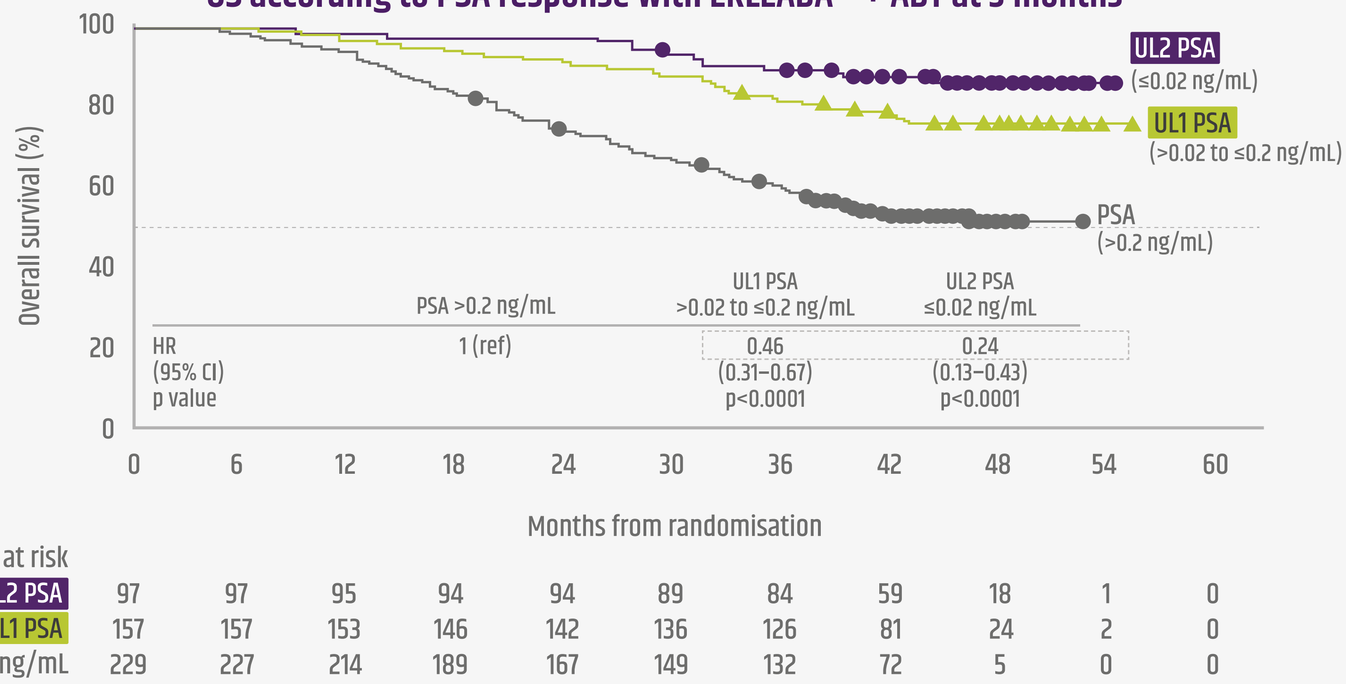
UL2 PSA (≤0.02 ng/mL) is 10x lower than the current threshold for undetectable PSA[2,19]

OS according to undetectable PSA responses at 3 months

*Data from a post-hoc analysis of TITAN;[19] TITAN was a double-blind, randomised, placebo-controlled international Phase III study evaluating ERLEADA® + ADT vs. placebo + ADT in patients with mHSP (N=1052; ERLEADA® + ADT [n=525], placebo + ADT [n=527]).[2] Evaluable PSA responses in this analysis included 515 patients on ERLEADA® + ADT and 520 patients on placebo + ADT. 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.[19]

ERLEADA® + ADT takes undetectable (UL1 and 2) PSA responses in mHSPC to a new low[19]

OS according to PSA response with ERLEADA® + ADT at 3 months[19]



No. at risk											
UL2 PSA	97	97	95	94	94	89	84	59	18	1	0
UL1 PSA	157	157	153	146	142	136	126	81	24	2	0
PSA >0.2 ng/mL	229	227	214	189	167	149	132	72	5	0	0

Adapted from Merseburger AS, *et al*. 2023.[19]

ERLEADA® + ADT reduced the risk of death in patients achieving a UL1 or 2 PSA response at 3 months vs. patients not achieving such a response[19]

Undetectable PSA (UL1 and 2)

UL1 PSA
54%
reduced risk of death [19]

UL2 PSA
76%
reduced risk of death [19]

ERLEADA® demonstrates greater affinity to ARs and exhibits rapid disease control vs. enzalutamide in preclinical models[20]

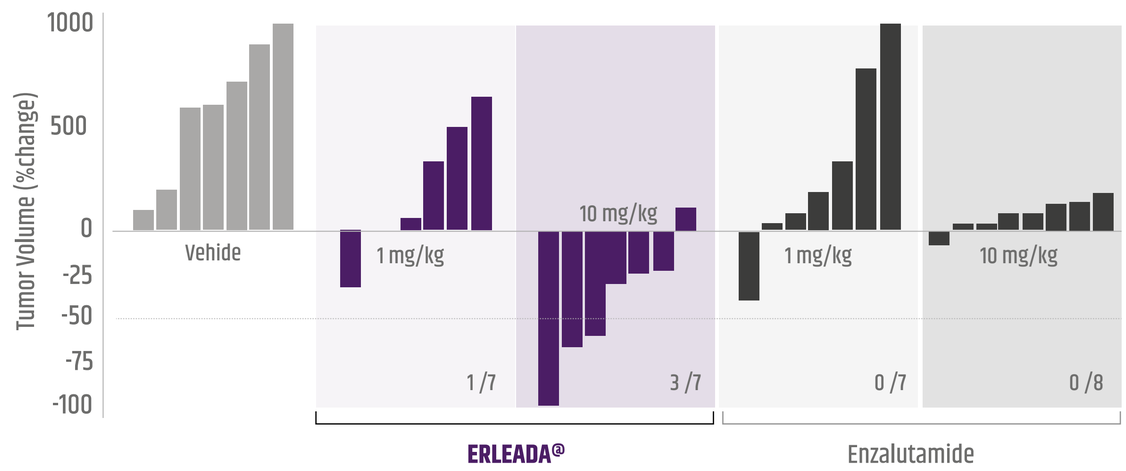
LNCaP/AR(cs) xenograft tumor-bearing mice treated with ERLEADA® showed:[20]

Higher AR binding affinity vs. enzalutamide in a competitive binding assay against ^{18}F-FDHT in **LNCaP/AR(cs) cells**[20]

>50% reduction in tumor volume in ~40% of xenografts vs. none with enzalutamide and vehicle, at the same dosing level (10 mg/kg)[20]

Agent	IC_{50} ± SEM (nmol/L)
^{18}F-FDHT	11.5 ± 2
ARN-509 (ERLEADA®)	16.0 ± 2.1
MDV3100 (enzalutamide)	21.4 ± 4.4
Bicalutamide	160 ± 29

Individual LNCaP/AR (cs) xenografts, Day 28 (castrate males)[20]



Adapted from Clegg NJ, et al. 2012.[20]

Reductions in PSA levels can have a beneficial impact on patients' emotional and physical wellbeing[21,22]

Elevated PSA levels can be a source of anxiety for patients with prostate cancer[21]

Increased PSA levels can cause physical and emotional distress, **impacting patients' overall well-being**[21]

Many patients document the results of their PSA tests and watch for changes[23]

A drop in PSA levels is often accompanied by a sense of relief, **creating a positive impact on how patients feel about their prostate cancer**[21,22]

Upfront use of ERLEADA® + ADT extends its benefits through to the next line of therapy[3,24]

ERLEADA® + ADT reduces the risk of second progression or death (PFS2) vs. placebo + ADT*[3,24]

38%

reduction in the risk of second progression or death

Median not reached with ERLEADA® + ADT vs. 44.0 months with placebo + ADT

(HR=0.62; 95% CI: 0.51–0.75; p<0.0001)*[3]

High-volume mHSPC

33% reduction

in the risk of second progression or death

Median time not reached vs. 40.3 months with placebo + ADT

(HR=0.67; 95% CI: 0.53–0.86; p=0.001)†[24]

Low-volume mHSPC

41% reduction

in the risk of second progression or death

Median time not reached for either arm

(HR=0.59; 95% CI: 0.38–0.91; p=0.02)†[24]

In TITAN,* ERLEADA® + ADT reduced the frequency of AR aberrations vs. placebo + ADT at the end of treatment (48% vs. 67%, respectively)[25]

- AR aberrations are a key step in the progression towards castration resistance[26]
- After progression to mCRPC, the **opportunity to prescribe ERLEADA® + ADT is lost forever**[1,10,11,16,17]
  - 21% of patients who discontinued ERLEADA® + ADT for progressive disease received abiraterone acetate + prednisone or enzalutamide as their first subsequent therapy‡[3]

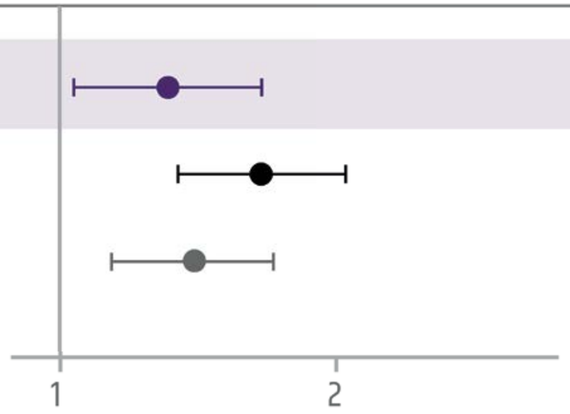
*Data from TITAN, a double-blind, randomised, placebo-controlled international Phase III study evaluating ERLEADA® + ADT vs. placebo + ADT in patients with mHSPC, regardless of their disease stage at baseline (N=1052). Dual primary endpoints of the TITAN study were rPFS (estimated as the time from randomisation to first imaging-based documentation of disease progression or death, whichever occurred first) and OS (time from randomisation to the date of death from any cause). Median follow-up of 44.0 months.[2,3] †Post-hoc analysis of TITAN.[24] ‡Abiraterone acetate and enzalutamide are indicated in patients who progress to mCRPC.[10,11] For the full indications, please see the respective SmPCs. Of the patients who discontinued ERLEADA® + ADT in the TITAN study, 14.5% received abiraterone acetate + prednisone and 6.5% received enzalutamide as their first subsequent therapy.[3]

ERLEADA® + ADT has an established and generally well-tolerated safety profile at nearly 4 years' median follow-up*[1,3]

In a network meta-analysis on the safety of systemic treatments in mHSPC, **ERLEADA® + ADT had the lowest relative risk of grade ≥3 AEs and serious AEs,** vs. other doublet and triplet regimens[27]

Relative risk for aggregated outcomes for serious AEs following systemic therapies vs. ADT alone[27]

Treatments	RR (95% CrI)	p value (RR<1)
ERLEADA® + ADT	1.26 (1.03–1.53)	1.3
Enzalutamide + ADT	1.54 (1.28–1.84)	0.0
AAP + ADT	1.33 (1.12–1.57)	0.1



Adapted from Di Maio M, *et al*. 2023.[27]

TEAEs of interest in the safety population

*The following AEs occurred in ≥5% of patients in the TITAN safety population, after median follow-up of 44.0 months: rash (17.6% vs. 2.3% vs. 11.1%); pruritus (8.2% vs. 2.5% vs. 3.8%); fatigue (13.5% vs. 8.7%vs. 6.7%); hot flush (12.8% vs. 9.9% vs. 1.4%) and hypertension (5.3% vs. 4.0% vs. 2.4%) of all grades were observed with ERLEADA® + ADT, placebo + ADT and crossover (placebo to ERLEADA®) + ADT, respectively.[28] For more detailed safety information, please refer to the Summary of Product Characteristics.[1] Post-marketing reports of SCARs including drug reaction with eosinophilia and systemic symptoms (DRESS) and Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), which can be life-threatening or fatal, have been observed in association with ERLEADA® treatment.[1] For more information, please refer to SmPC sections 4.4 and 4.8.

ERLEADA® + ADT has an established and generally well-tolerated safety profile at nearly 4 years' median follow-up*[1,3]

Category	ERLEADA® + ADT (n=524)		Placebo + ADT (n=527)		Crossover to ERLEADA® + ADT (n=208)	
Median treatment duration, months (range)[†]	39.3 (0–55.7)		20.2 (0.1–37.0)		15.4 (0.6–18.2)	
Total exposure, patient-years	**1358.9**		**793.3**		**243.6**	
TEAEs by group term, event (event rate/100 patient-years of exposure)[‡]	All grades	Grade 3–4	All grades	Grade 3–4	All grades	Grade 3–4
Any TEAE of interest	543 (40.3)	103 (7.6)	178 (22.4)	21 (2.7)	102 (41.9)	16 (6.5)
Skin rash[¶]	331 (24.4)	40 (2.9)	66 (8.3)	5 (0.6)	44 (18.1)	8 (33.3)
Fracture[‖]	83 (6.1)	21 (1.5)	33 (4.2)	4 (0.5)	5 (2.1)	0
Fall	63 (4.6)	9 (0.7)	54 (6.8)	5 (0.6)	14 (5.7)	0
Ischaemic heart disease[#]	45 (3.3)	21 (1.5)	13 (1.6)	5 (0.7)	1 (0.4)	1 (0.4)
Ischaemic cerebrovascular disorders**	18 (1.3)	11 (0.8)	10 (1.3)	2 (0.3)	7 (2.9)	7 (2.8)
Seizure[††]	3 (0.2)	1 (0.1)	2 (0.3)	0	0	0

Table from Chi KN, *et al*. 2021.[3]

*Median follow-up of 44 months.[3] [†]Patients received treatment until disease progression or unacceptable toxicity.[3] [‡]Event rate per 100 patient-years of exposure is calculated as 100 times the number of distinct events with the group term/total patient-years of exposure (total days of exposure/365.25) for the treatment group. AEs occurred from the time of the first dose of the study intervention through 30 days after the last dose. AEs were graded according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.0.3. One patient who was assigned to the apalutamide group withdrew consent before treatment.[3] [§]The worst toxicity grade is included. Patients with missing toxicity grades were counted in the all-grade column.[3] [¶]Skin rash was a grouped term including rash, maculopapular rash, conjunctivitis, dermatitis, stomatitis, pruritic rash, urticaria, papular rash, skin exfoliation, blister, mouth ulceration, drug eruption, erythema multiforme, exfoliative rash, toxic skin eruption, papule, skin reaction, butterfly rash, generalized exfoliative dermatitis, genital rash, erythematous rash, macular rash, systemic lupus erythematosus rash, oral mucosal blistering, follicular rash, pustular rash, and vesicular rash.[3] [‖]Fracture was a grouped term including rib fracture, spinal compression fracture, hand fracture, femoral neck fracture, foot fracture, femur fracture, thoracic vertebral fracture, traumatic fracture, upper limb fracture, wrist fracture, ankle fracture, fracture, hip fracture, spinal fracture, radius fracture, acetabulum fracture, fracture pain, clavicle fracture, comminuted fracture, compression fracture, forearm fracture, humerus fracture, patella fracture, pelvic fracture, sternal fracture, stress fracture, ulna fracture, fibula fracture, lower limb fracture, skull fracture, and tibia fracture.[3] [#]Ischemic heart disease was a group term including angina pectoris, myocardial infarction, acute myocardial infarction, coronary artery stenosis, coronary artery arteriosclerosis, myocardial ischemia, coronary artery disease, coronary artery occlusion, acute coronary syndrome, abnormal cardiac stress test, ischemic cardiomyopathy, unstable angina, and increased troponin.[3] **Ischemic cardiovascular disorder was a group term including cerebrovascular accident, transient ischemic attack, ischemic stroke, cerebrovascular disorder, lacunar infarction, cerebral ischemia, hemiplegia, vascular encephalopathy, carotid artery stenosis, and carotid arteriosclerosis.[3] [††]Seizure was a group term including seizure and tongue biting.[3]

ERLEADA® + ADT does not compromise HRQoL from baseline and vs. placebo + ADT[3,29,30]

Upfront use of ERLEADA® + ADT:

Maintains HRQoL from baseline and vs. placebo + ADT*[3,29]

Preserves low baseline pain and fatigue scores at almost 2 years' median follow-up†[29]

Offers patients with pain at baseline **29% more chance of improvement of their worst pain** vs. placebo + ADT (p=0.02)‡[30]

*HRQoL outcomes were measured using the Brief Pain Inventory-Short Form (BPI-SF), the Brief Fatigue Inventory (BFI), Functional Assessment of Cancer Therapy–Prostate (FACT-P; version 4), and the EuroQoL five dimensions, five-levels questionnaire (EQ-5D-5L).[3,29] †Median follow-up for time to pain related endpoints ranged from 19.4 to 22.1 months.[29] ‡Median follow-up time for pain progression was 22.1 months for the ERLEADA® + ADT group and 21.7 months for the placebo + ADT group.[30]

The established efficacy of ERLEADA® can be conveniently obtained without corticosteroids[1,10,31,32]

ERLEADA® + ADT does not require long term steroid exposure or monitoring of hypokalaemia and liver function,[1,10] helping patients to potentially avoid additional hospital visits[33]

ERLEADA® + ADT vs. other approved NHTs in the treatment of mHSPC*

NHTs for the treatment of mHSPC*	ERLEADA® + ADT[†1]	Enzalutamide + ADT[11]		AAP + ADT[10,34]	
Available tablet strengths	60 mg	80 mg	40 mg	500 mg	250 mg
Tablets per day	●●●●	●●	●●●●	●●	●●●●
No corticosteroids and associated monitoring	✓	✓		✗	
Taken with or without food	✓	✓		✗ without food	
No chemotherapy	✓	✓		✓	
Alternate approved methods of administration	✓	✗		^	

*Product comparisons with regard to efficacy and safety cannot be made in the absence of head-to head clinical studies. This presentation is not intended to compare the relative efficacy or safety of the treatments. Please refer to the Summary Product Characteristics of each agent for dosage and administration.[1,10,11] † ERLEADA® can be dispersed in non-fizzy water and then mixed with one of the following non-fizzy beverages or soft foods; orange juice, green tea, applesauce, or drinkable yogurt.[1]

Real-world data favour upfront use of ERLEADA® + ADT
vs. either enzalutamide or abiraterone acetate in patients with mHSPC[5-9]

Prolongs OS,[*5–7] achieves more rapid PSA90 responses,[†8,9] and delays TTCR[*5] vs. other approved NHTs[‡] in the real-world setting

Offers the lowest relative risk of Grade ≥3 AEs and serious AEs vs. other doublet and triplet regimens[27]

Can deliver undetectable PSA responses, associated with improved clinical outcomes vs. not achieving such responses[§19]

Maintains HRQoL and stable energy levels from baseline[§3,29,30]

Keeps subsequent treatment options open on disease progression[1,3,10,11,16,17,24]

*Data from retrospective, observational cohort studies which examined the impact of approved NHT treatment regimens (ERLEADA®, enzalutamide, or abiraterone acetate) on clinical outcomes in real-world clinical practice in the United States.5–7 †Data are from electronic medical records from PPS Analytics including data from US community urology practices linked with administrative claims from the Komodo Health Solutions Research Database; ≥PSA90 was defined as the earliest attainment of ≥90% decline in PSA relative to most recent pre-index PSA. Patients were followed from index date to earliest of index regimen discontinuation, treatment switch, end of clinical activity or end of data availability.[8,9] ‡Approved NHT regimens include enzalutamide and abiraterone acetate.[10,11] §Data from TITAN, a double-blind, randomised, placebo-controlled, international Phase III study evaluating ERLEADA® + ADT vs. placebo + ADT in patients with mHSPC, regardless of their disease stage at baseline (N=1052). Dual primary endpoints were rPFS (estimated as the time from randomisation to first imaging-based documentation of disease progression or death, whichever occurred first) and OS (time from randomisation to the date of death from any cause). Median follow-up was 44.0 months.[2,3]

ERLEADA® prescribing information

Scan the QR code to view the full SmPC

Abbreviations

18F-FDHT, 16b-[18F]fluoro5-a-DHT (radioisotope fluorine F18)
1L, first-line
2L, second-line
AAP, abiraterone acetate + prednisone/prednisolone
ADT, androgen deprivation therapy
AE, adverse event
aHR, adjusted hazard ratio
AR, androgen receptor
BCR, biochemical recurrence
CI, confidence interval
CR, castration resistance
CrI, credible interval
EAU, European Association of Urology
ESMO, European Society for Medical Oncology
HR, hazard ratio
HRQoL, health-related quality of life
IC50, half-maximal inhibitory concentration
LPC/LAPC, localised prostate cancer/locally advanced prostate cancer
LNCaP, Lymph Node Carcinoma of the Prostate
mCRPC, metastatic castration-resistant prostate cancer
mHSPC, metastatic hormone-sensitive prostate cancer
NHT, novel hormonal therapy
N/A, not applicable
nmCRPC, non-metastatic castration-resistant prostate cancer
OS, overall survival
PC, prostate cancer
PSA, prostate specific antigen
rPFS, radiographic progression-free survival
RR, relative risk
SEM, standard error of mean
TEAE, treatment-emergent adverse event
TTCR, time to castration resistance
UL1, ultra-low 1
UL2, ultra-low 2
US, United States

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