Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

PI R

Push back early with ERLEADA® + ADT. Extend life.[1–4]

Real-world data favour first-line ERLEADA® in patients with mHSPC, offering superior clinical outcomes vs. abiraterone acetate[5–7]

ADT, androgen deprivation therapy; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer; OS, overall survival; PSA, prostate-specific antigen.

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-444953 | Date of preparation: March 2024

Meet Tarek*

A 64-year-old restaurant owner

Current diagnosis: Metachronous mHSPC

Disease volume: Low† (3 bone metastases)

Disease risk: High‡

PSA: 16 ng/L

Gleason score: 8 (4+4)

Comorbidities: Moderate hepatic impairment (Child-Pugh B)§

Prognosis: Life expectancy of around 4 years[8]

Tarek wants to slow the progression of the disease, without slowing down himself

He fears that the side effects of treatment may prevent him from running his business

So, how can first-line ERLEADA® + ADT help patients like Tarek?*

ADT, androgen deprivation therapy; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen. *Fictional patient based on the clinical characteristics of mHSPC patients included in the TITAN study.[2,3] †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.[2] ‡In TITAN, patients were considered to be high risk if they had a Gleason score of ≥8, ≥1 lesion on bone scanning and the presence of measurable visceral metastasis.[2,3] §No dose adjustment is necessary for patients with baseline mild or moderate hepatic impairment (Child-Pugh Class A and B, respectively).[1]

Help extend Tarek's median OS with ERLEADA® + ADT
vs. placebo + ADT[3,4,9]

TITAN overall population with mHSPC*

35%

reduction in the risk of death

Median not reached for ERLEADA® + ADT vs. 52.2 months with placebo + ADT

(HR=0.65; 95% CI: 0.53–0.79; p<0001)[3]

Overall population with mHSPC*

ERLEADA® + ADT

~6 years

(71.5 months)

predicted median OS

(vs. 39.5 months with placebo + ADT)[4]

Low-volume mHSPC†

ERLEADA® + ADT

9.4 years

(113.1 months)

predicted median OS

(vs. 47.3 months with placebo + ADT)[4]

In TITAN, ERLEADA® + ADT provided a

78% reduction in the risk of death in patients like Tarek with low-volume metachronous mHSPC vs. placebo + ADT[9]

Median not reached for either arm (HR=0.22; 95% CI: 0.09–0.55; p=0.001)‡[9]

ADT, androgen deprivation therapy; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen. *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 6 models, and the best fit was determined using statistical and visual criteria.[4] †Predicted median OS in high-volume mHSPC with ERLEADA® + ADT was 4.3 years (51.9 months) vs. 33.8 months with placebo + ADT.[4] ‡*Post-hoc* analysis of TITAN.[9]

Help prolong Tarek's OS with first-line ERLEADA® + ADT

vs. AAP + ADT[5]

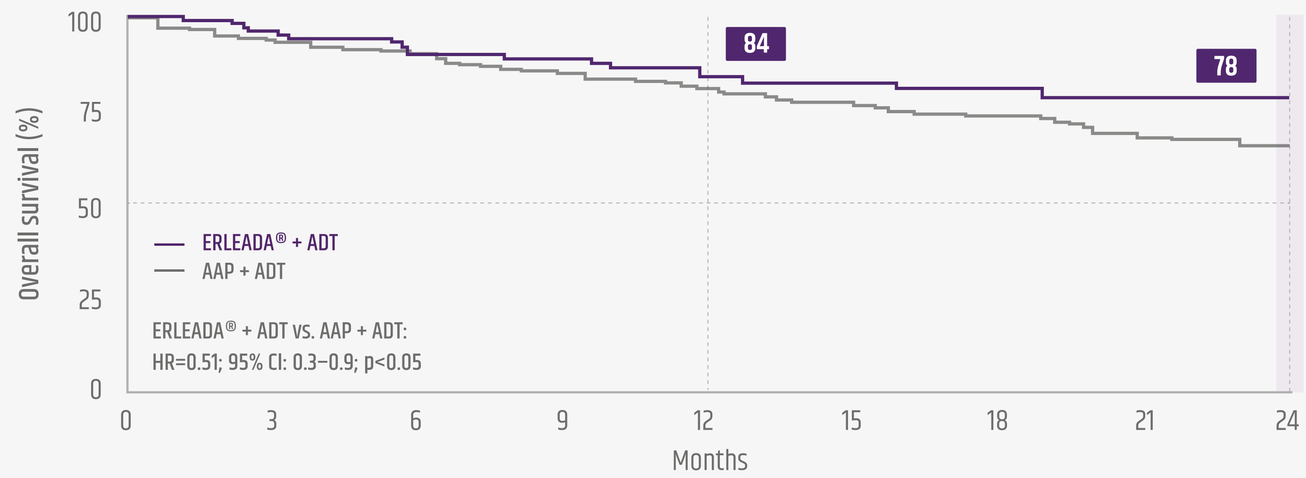
Real-world data* demonstrate that ERLEADA® + ADT reduces the risk of death

vs. AAP + ADT (aHR=0.51; 95% CI: 0.29–0.9; p<0.05)[5]

49%

reduction in the risk of death
vs. AAP + ADT[5]

Overall survival (%)[5]



No. at Risk									
ERLEADA® + ADT (N=165)	**144**	**132**	**107**	**85**	**63**	**51**	**37**	**23**	**12**
AAP + ADT (N=1064)	555	490	429	351	270	206	153	102	70

Adapted from Maughan BL, *et al*. 2024.[5]

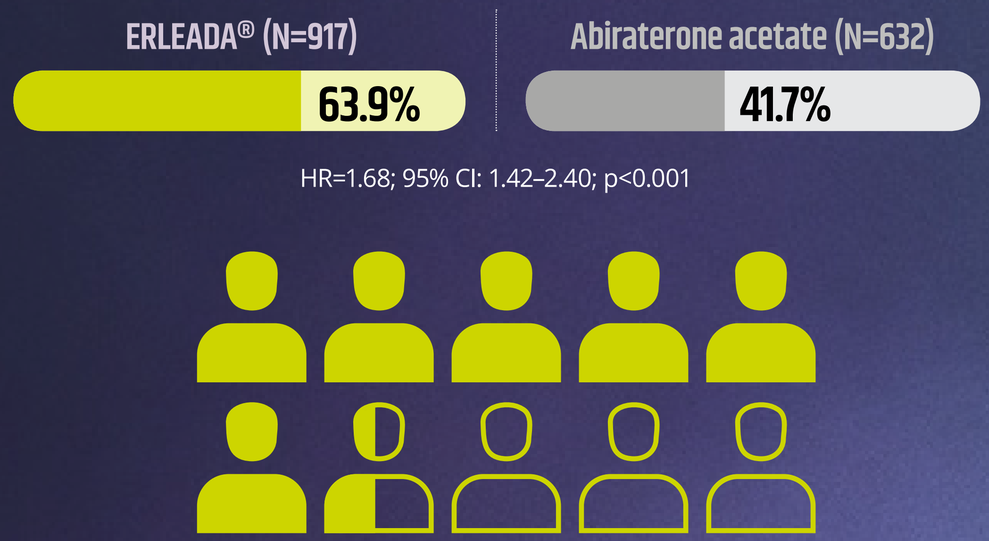
AAP, abiraterone acetate + prednisone; ADT, androgen deprivation therapy; aHR, adjusted hazard ratio; CI, confidence interval; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; NHT, novel hormonal therapy; OS, overall survival; PSA, prostate-specific antigen. *Data from a retrospective, observational cohort study assessing 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 States (N=4622). Kaplan–Meier method was used to estimate OS, PSA reduction and castration resistance 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]

Help Tarek achieve rapid and deep PSA responses with ERLEADA®[7]

In the real-world setting,* more mHSPC patients on ERLEADA® obtained PSA90 responses at 6 months vs. abiraterone acetate†[7]

Shorter median time to PSA90 with ERLEADA®[7]

More patients achieve PSA90 at 6 months with ERLEADA®[7]



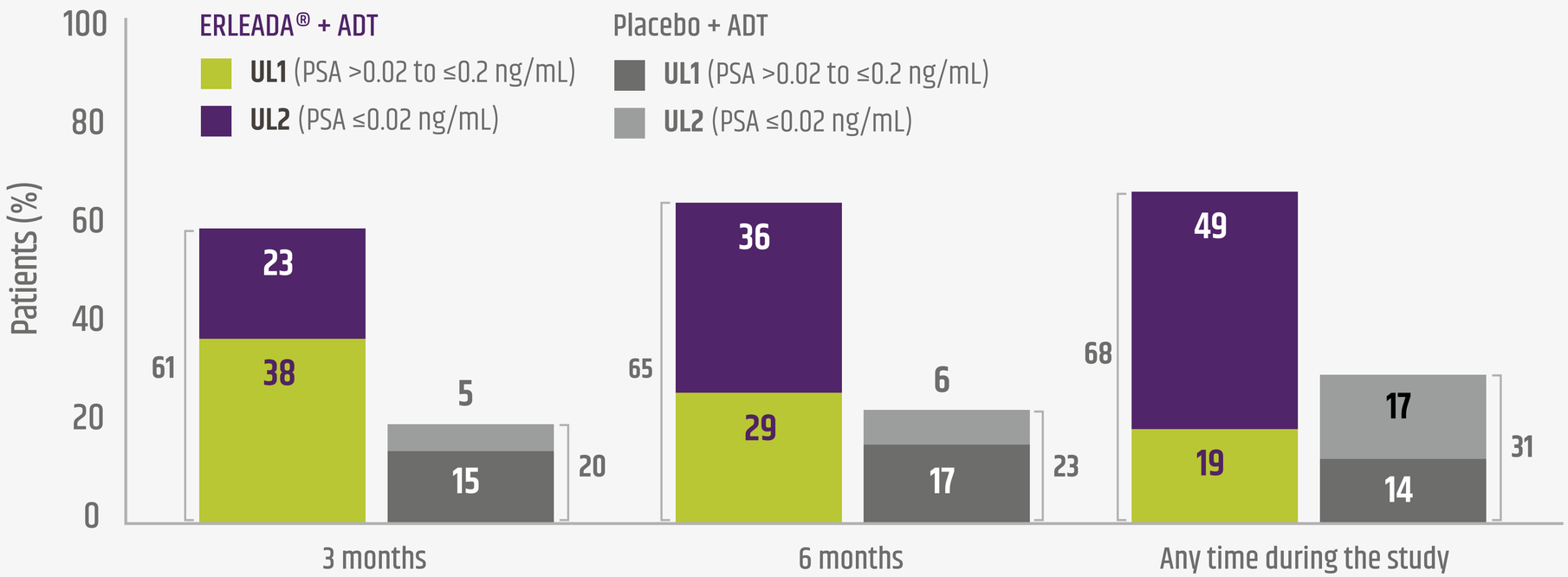
ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; US, United States. *Data are from electronic medical records from PPS Analytics 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.[7] †Concurrent prednisone use was not required for inclusion in the abiraterone acetate cohort.[7]

Provide Tarek with the opportunity to attain an undetectable PSA response with ERLEADA® + ADT[10]

More than double the number of patients on ERLEADA® + ADT achieve undetectable (UL1 [PSA >0.02 to ≤0.2 ng/mL] and UL2 [PSA ≤0.02 ng/mL]) PSA responses at 3 months vs. those on placebo + ADT*[10]

- Achieving an undetectable PSA response at 3 months with ERLEADA® + ADT is associated with improved OS vs. not achieving a response[10]
- UL2 PSA (≤0.02 ng/mL) is 10x lower than the current threshold for undetectable PSA[2,10]

Patients achieving undetectable (UL1 and 2) PSA responses over time (%)[10]



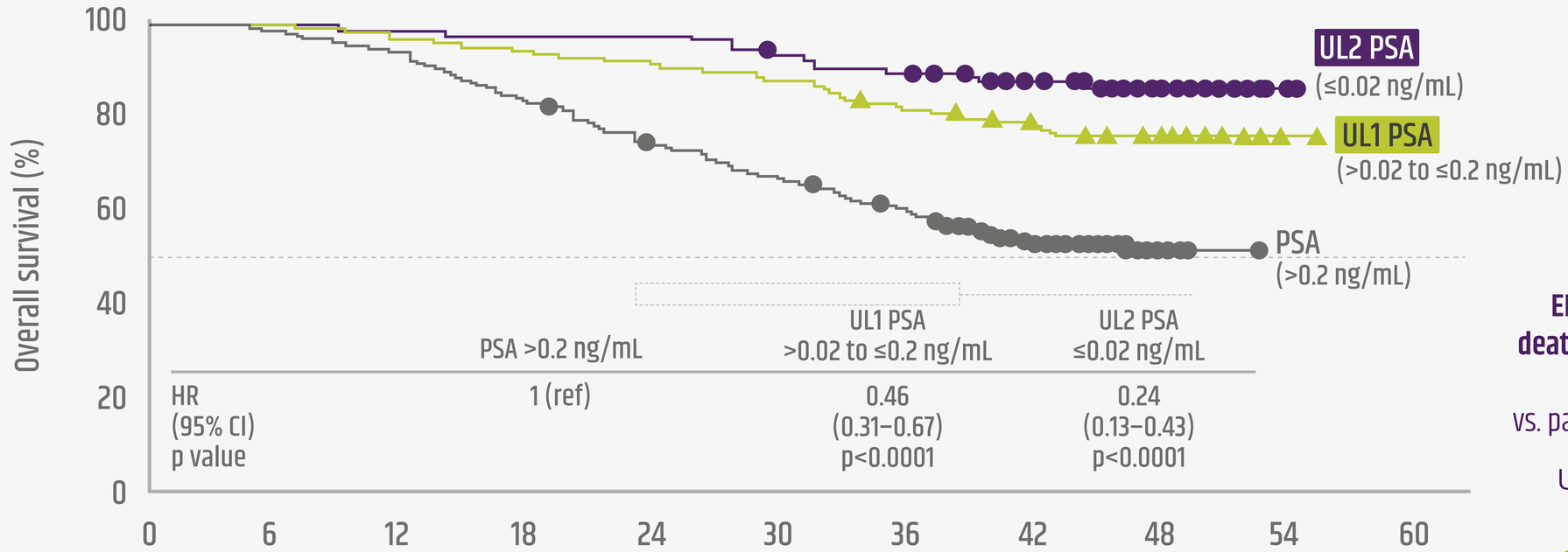
(N=1052; evaluable PSA response in: n=515, ERLEADA® + ADT; n=520, placebo + ADT)[10]
Adapted from Merseburger AS, *et al*. 2023.[10]

OS according to undetectable PSA responses at 3 months +

ADT, androgen deprivation therapy; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival; UL1, ultra-low 1; UL2, ultra-low 2. *Data are from a *post-hoc* analysis of TITAN; TITAN was 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] 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.[10]

Offer Tarek with the opportunity to attain undetectable (UL1 and 2) PSA responses with ERLEADA® + ADT[10]

OS according to PSA response with ERLEADA® + ADT at 3 months[10]



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

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[10]

Undetectable PSA (UL1 and 2)

UL1 PSA
54%
reduction in the risk of death

UL2 PSA
76%
reduction in the risk of death

Adapted from Merseburger AS, *et al*. 2023.[10]

ADT, androgen deprivation therapy; OS, overall survival; PSA, prostate-specific antigen; UL1, ultra-low 1; UL2, ultra-low 2.

Reductions in PSA levels can have a beneficial impact on Tarek's emotional and physical wellbeing[11,12]

Elevated PSA levels can be a source of anxiety for patients with prostate cancer[11]

Increased PSA levels can cause physical and emotional distress, **impacting patients' overall wellbeing**[11]

Many patients document the results of their PSA tests and watch for changes[13]

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**[11,12]

HRQoL, health-related quality of life; OS, overall survival; PSA, prostate-specific antigen.

Upfront use of ERLEADA® + ADT keeps your and Tarek's subsequent treatment options open[3,9]

ERLEADA® + ADT reduces the risk of second progression or death (PFS2) vs. placebo + ADT, regardless of disease volume*[3,9]

38%

reduction in the risk of second progression or death

Median not reached with ERLEADA® + ADT vs. 44.0 months with placebo + ADT[3]

(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 not reached with ERLEADA® + ADT vs. 40.3 months with placebo + ADT

(HR=0.67; 95% CI: 0.53–0.86; p=0.001)†[9]

Low-volume mHSPC

41% reduction in the risk of second progression or death

Median not reached for either arm

(HR=0.59; 95% CI: 0.38–0.91; p=0.02)†[9]

Low-volume metachronous mHSPC, like Tarek

78% reduction in the risk of second progression or death

Median not reached for either arm

(HR=0.22; 95% CI: 0.09–0.56; p=0.002)†[9]

In TITAN,* ERLEADA® + ADT reduced the frequency of AR aberrations vs. placebo + ADT at the end of treatment‡[14]

- AR aberrations are a key step in the progression towards castration resistance[15]
- After progression to mCRPC, the opportunity to prescribe ERLEADA® + ADT is lost forever[1,16–19]
  - 15% of patients who discontinued ERLEADA® + ADT for progressive disease received abiraterone acetate + prednisone as their first subsequent therapy§[3]

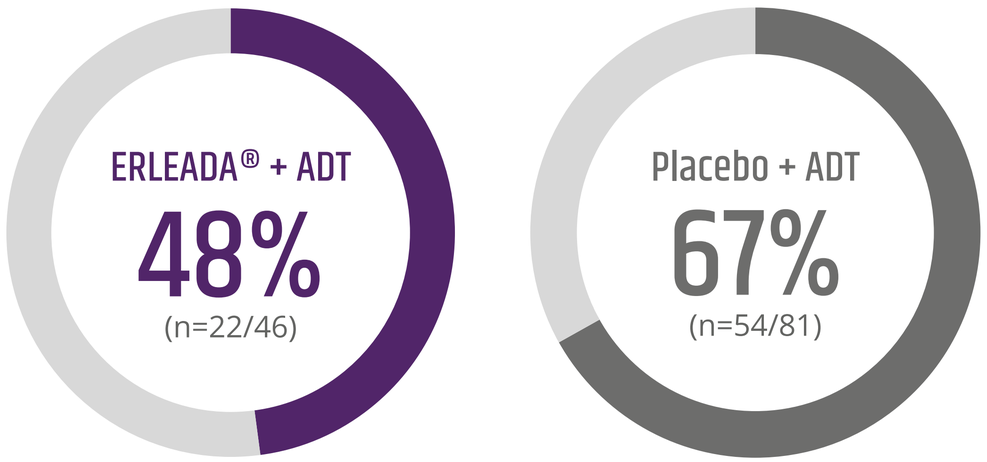
ADT, androgen deprivation therapy; AR, androgen receptor; HRQoL, health-related quality of life; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival. *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.[9] ‡Frequency of AR aberrations at end of treatment (48% with ERLEADA® + ADT vs. 67% with placebo + ADT; p=0.04).[14] §Abiraterone acetate is indicated in patients who progress to mCRPC.[16] Of the patients who discontinued ERLEADA® + ADT in the TITAN study, 14.5% received abiraterone acetate + prednisone.[3] For the full abiraterone acetate indication, please see the SmPC.

Upfront use of ERLEADA® + ADT keeps subsequent treatment options open[3,20]

ERLEADA® + ADT reduces the frequency of AR aberrations vs. placebo + ADT[2]

- In TITAN,* AR aberrations commonly associated with AR-signalling therapy resistance in mCRPC were significantly lower in patients treated with ERLEADA® + ADT vs. placebo + ADT (p=0.04) at the end of treatment[2]

Patients with AR aberrations at end of treatment (%)[2]



Adapted from Chi KN, *et al*. 2019.[2]

AR aberrations are a key step in the progression towards castration resistance[15]

After progression to mCRPC, the opportunity to prescribe ERLEADA® + ADT is lost forever[1, 16-19]

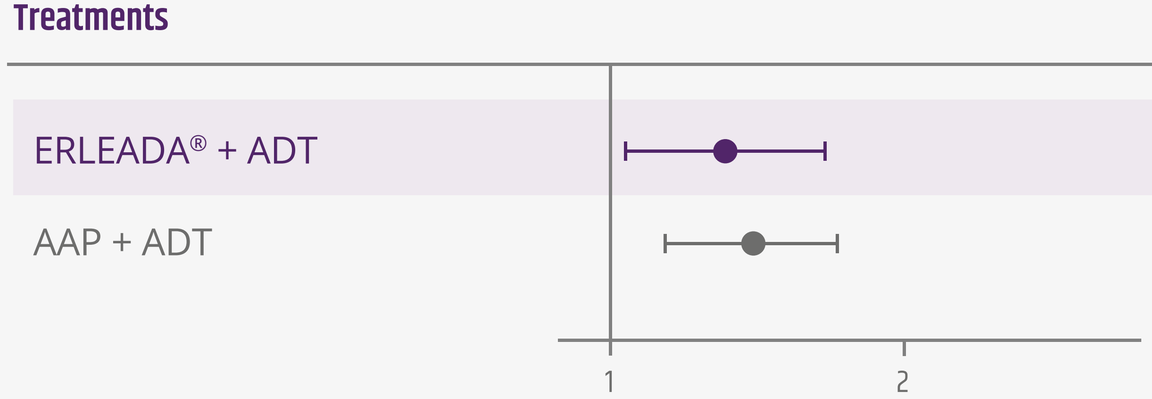
15% of patients in TITAN who discontinued ERLEADA® + ADT for progressive disease received abiraterone acetate + prednisone as their first subsequent therapy†[3]

ADT, androgen deprivation therapy; AR, androgen receptor; HRQoL, health-related quality of life; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival. *TITAN was 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] †Abiraterone acetate is indicated in patients who progress to mCRPC.[16] Of the patients who discontinued ERLEADA® + ADT in the TITAN study, 14.5% received abiraterone acetate + prednisone.[3] For the full abiraterone acetate indication, please see the SmPC.

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[21]

Relative risk for aggregated outcomes for serious AEs following systemic therapies vs. ADT alone[21]



Adapted from Di Maio M, *et al*. 2023.[21]

TEAEs of interest in the safety population

ADT, androgen deprivation therapy; AE, adverse event, CrI, credible interval; HRQoL, health-related quality of life; RR, relative risk; OS, overall survival; PSA, prostate-specific antigen; SCARS, severe cutaneous adverse reactions; TEAE, treatment-emergent AE. *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.[22] For more detailed safety information, please refer to the Summary of Product Characteristics [SMPC].[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 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]

ADT, androgen deprivation therapy; AE, adverse event; TEAE, treatment-emergent AE. *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, generalised 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] #Ischaemic heart disease was a group term including angina pectoris, myocardial infarction, acute myocardial infarction, coronary artery stenosis, coronary artery arteriosclerosis, myocardial ischaemia, coronary artery disease, coronary artery occlusion, acute coronary syndrome, abnormal cardiac stress test, ischaemia cardiomyopathy, unstable angina, and increased troponin.[3] **Ischaemic cardiovascular disorder was a group term including cerebrovascular accident, transient ischaemic attack, ischaemic stroke, cerebrovascular disorder, lacunar infarction, cerebral ischaemia, 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, allowing Tarek to continue cooking in his restaurant[3,23,24]

Upfront use of ERLEADA® + ADT:

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

View Data

Preserves low baseline pain and fatigue scores at almost 2 years' median follow-up†[23]

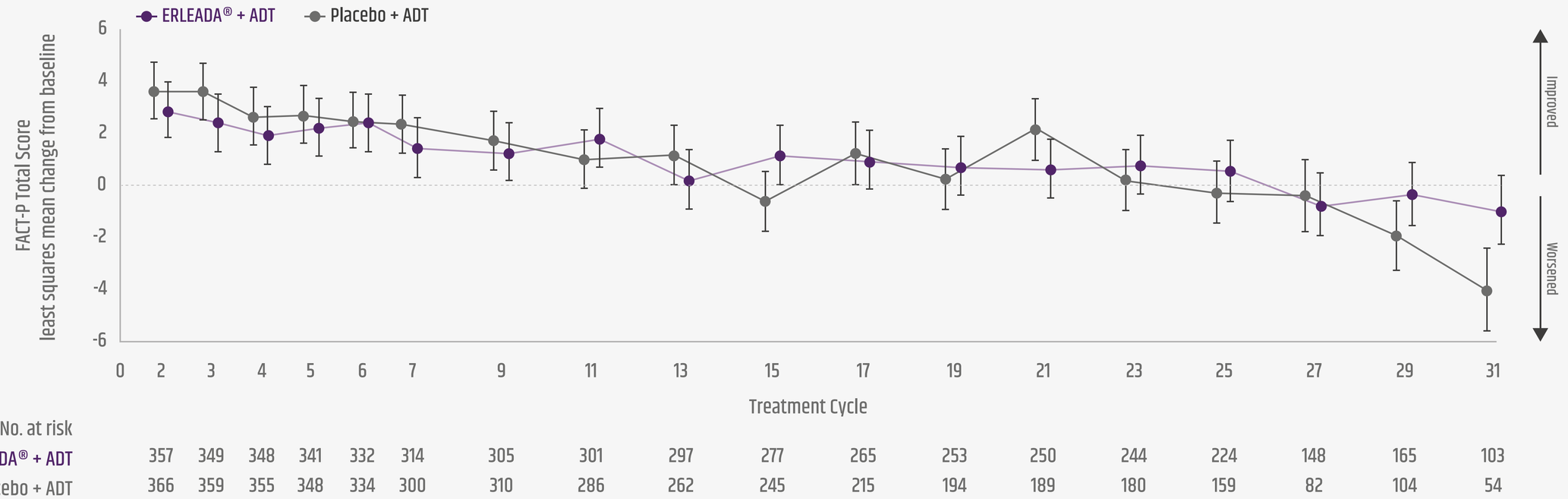
View Data

Offers patients with pain at baseline **29% more chance of improvement of their worst pain** vs. placebo + ADT (p=0.02)‡[24]

View Data

ADT, androgen deprivation therapy; EuroQoL, European quality of life; HRQoL, health-related quality of life; OS, overall survival; PSA, prostate-specific antigen. *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).[3,22] †Median follow-up for time to pain related endpoints ranged from 19.4 to 22.1 months.[22] ‡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.[24]

ERLEADA® + ADT maintains HRQoL from baseline and vs. placebo + ADT[3]

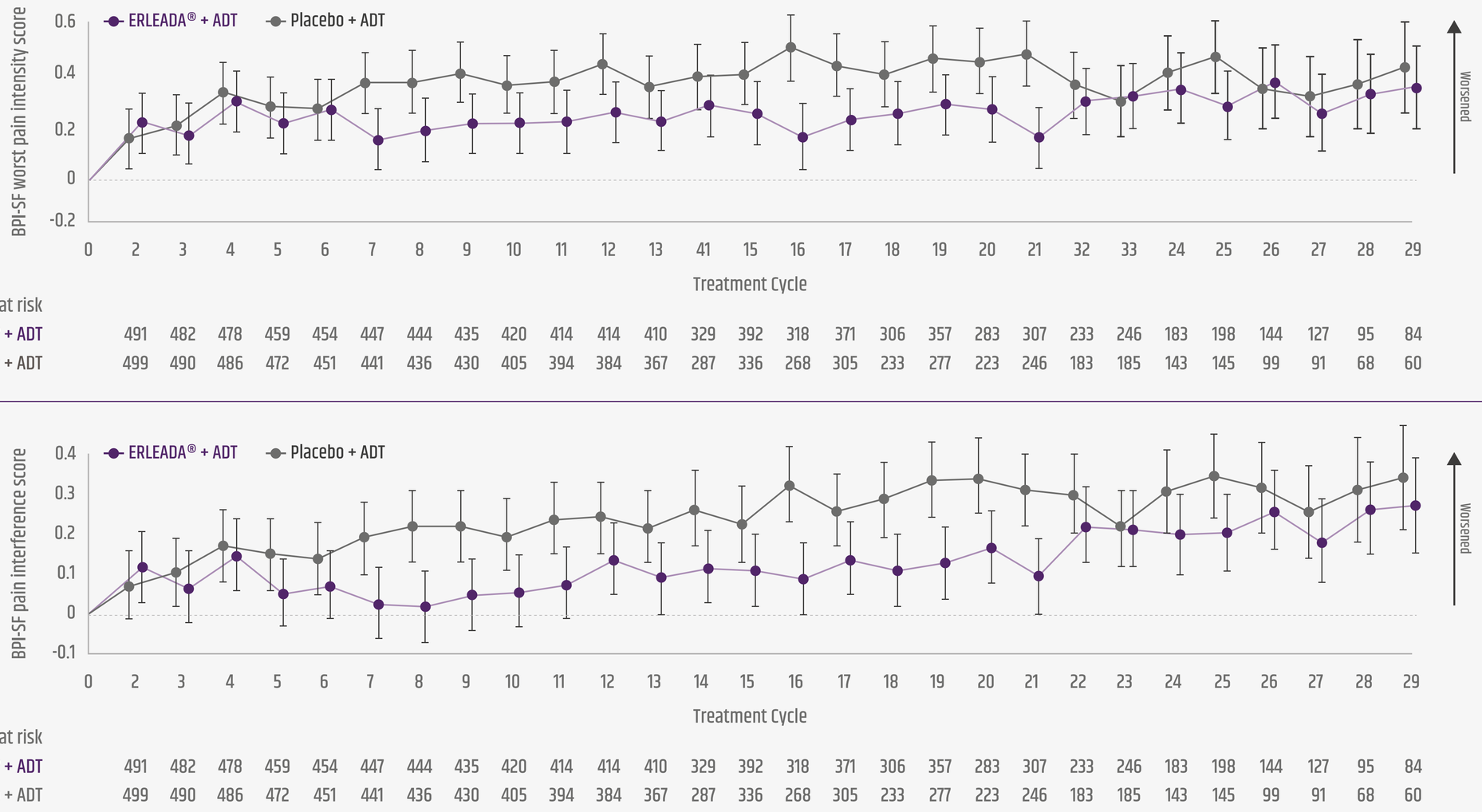


Adapted from Chi KN, *et al*. 2021.[3]

ADT, androgen deprivation therapy; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HRQoL, health-related quality of life.

ERLEADA® + ADT preserves low baseline pain and fatigue scores at almost 2 years' median follow-up*[23]

Patient-reported changes in pain from baseline by BPI-SF



Patient-reported changes in fatigue from baseline by BFI

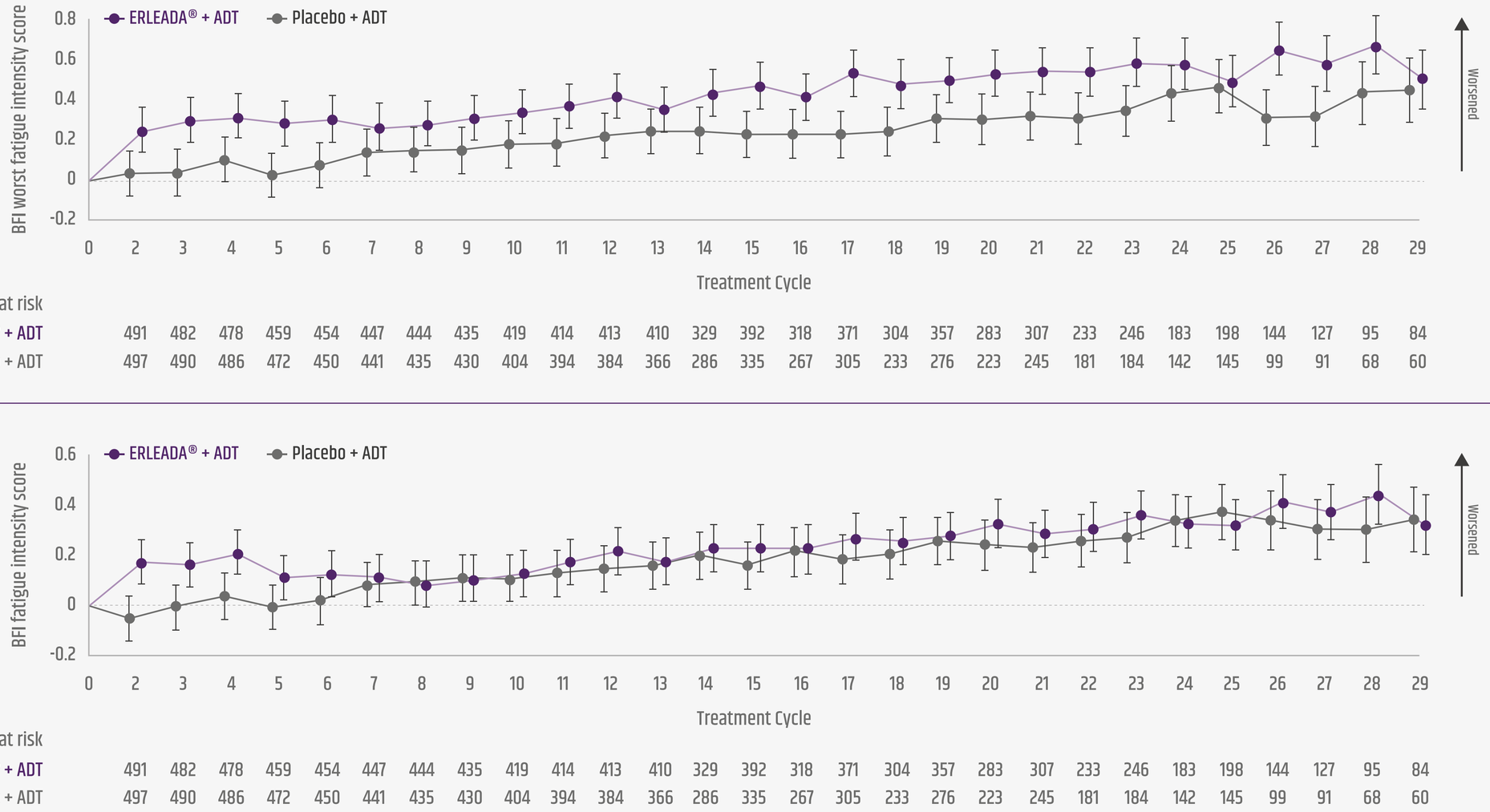
Adapted from Agarwal N, *et al.* 2019.[23]

ADT, androgen deprivation therapy; BFI, Brief Fatigue Inventory; BPI-SF, Brief Pain Inventory-Short Form. *Median follow-up for time to pain related endpoints ranged from 19.4 to 22.1 months.[23]

ERLEADA® + ADT preserves low baseline pain and fatigue scores at almost 2 years' median follow-up[23]

Patient-reported changes in pain from baseline by BPI-SF

Patient-reported changes in fatigue from baseline by BFI

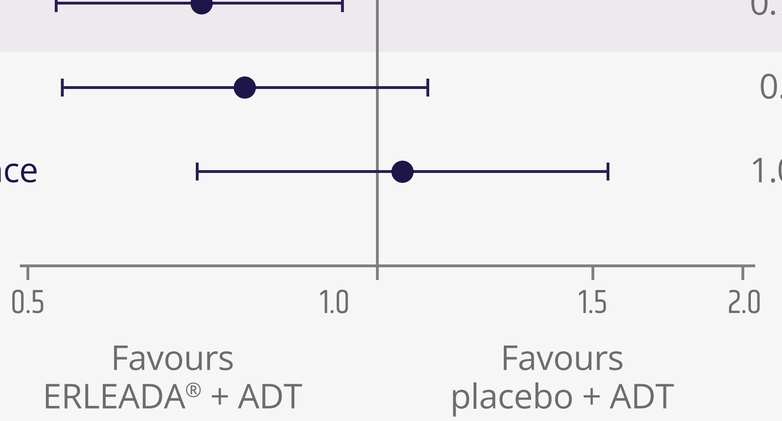


Adapted from Agarwal N, *et al*. 2019.[23]

ADT, androgen deprivation therapy; BFI, Brief Fatigue Inventory; BPI-SF, Brief Pain Inventory-Short Form.

ERLEADA® + ADT offers patients with pain at baseline 29% more chance of improvement of their worst pain vs. placebo + ADT*[24]

BPI pain end point	RR (95% CI)	ERLEADA® + ADT n/N	Placebo + ADT n/N	p value (RR<1)
BPI worst pain	0.71 (0.54–0.94)	89/301	65/308	0.02
BPI average pain	0.78 (0.5–1.10)	58/301	46/308	0.16
BPI pain interference	1.05 (0.71–1.57)	40/301	43/308	0.82



Adapted from Agarwal N, *et al*. 2021.[24]

ADT, androgen deprivation therapy; BPI, Brief Pain Inventory; RR, relative risk. *Analysis examined patients with pain at baseline who experienced a 2-point improvement on scale of 0–10 with treatment.[24]

Simplify Tarek's treatment with ERLEADA® tablet without corticosteroids[1,16,25,26]

ERLEADA® + ADT does not require long-term steroid exposure or monitoring of hypokalaemia and liver function,[1,16] helping patients like Tarek potentially avoid additional hospital visits vs. AAP + ADT[27]

NHTs for the treatment of mHSPC*	ERLEADA® + ADT[11]	AAP + ADT[16,28]	
Available tablet strengths	**60 mg**	**500 mg**	**250 mg**
Tablets per day	●●●●	●●	●●●●
No corticosteroids and associated monitoring	✓	✗	
Taken with or without food	✓	✗ without food only	
No chemotherapy	✓	✓	
Alternate approved methods of administration	✓	✗	

AAP, abiraterone acetate + prednisone; ADT, androgen deprivation therapy; HRQoL, health-related quality of life; NHT, novel hormonal therapy; OS, overall survival; PSA, prostate-specific antigen.
*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 of Product Characteristics of each agent for dosage and administration.[1,16] †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]

Choose ERLEADA® + ADT upfront in mHSPC to optimise your patients' treatment outcomes[2–7,9,10]

For patients like Tarek, first-line ERLEADA® + ADT:

- Prolongs OS*[5,6] and achieves more rapid PSA90 responses†[7] vs. abiraterone acetate in the real-world setting
- Offers the lowest relative risk of grade ≥3 AEs and serious AEs vs. other doublet and triplet regimens[21]
- Can deliver undetectable PSA responses as early as 3 months, associated with improved clinical outcomes vs. not achieving such responses‡[10]
- Maintains HRQoL and stable energy levels from baseline‡[3,23,24]
- Keeps subsequent treatment options open on disease progression[1,3,9,16–19]

ADT, androgen deprivation therapy; AE, adverse event; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PSA, prostate-specific antigen; rPFS radiographic progression-free survival. *Data from retrospective, observational cohort studies that examined the impact of approved NHT treatment regimens (ERLEADA®, enzalutamide, or AAP) on clinical outcomes in real-world clinical practice in the United States.[5,6] †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.[7] ‡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

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