

ERLEADA[®]: An effective treatment option for your mCSPC patients

Hear from an expert



Professor Axel Merseburger is the Chair of Urology at University Hospital Schleswig-Holstein, Germany. He is Chairman-elect for the European Scholarship Program and has authored over 300 articles investigating biomarkers for prostate, renal, and bladder cancer.

 **Erleada[®]**
(apalutamide) tablets



Mr V.G. is 55 years old and his history includes:

- Diagnostic laparoscopy for unclear colitis
- Liver and kidney cysts
- His mother had breast cancer
- Excision of left lower leg melanoma (20 years ago)

Mr V.G. experienced a gardening accident in the summer of 2019

Following his accident, he began experiencing:



Tingling sensations in his right hand



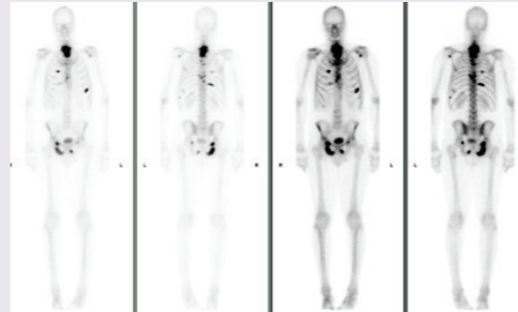
Pain corresponding with the C8 and D1 dermatomes on the right side of his body

After consulting his healthcare provider, conservative management was commenced but there was no improvement and the pain progressively worsened.

In January 2020 he underwent a thorough investigation:

- An MRI showed multiple malignancies in his vertebrae
- A blood test found prostate-specific antigen (PSA) levels of 158 ng/ml

After additional bone scans (see right) Mr V.G. was diagnosed with hormone-sensitive metastatic (lymphogenic and osseous) prostate carcinoma (mCSPC) in February 2020. His Gleason score was 4+5=9 and hemangioma (live metastases) was ruled out.

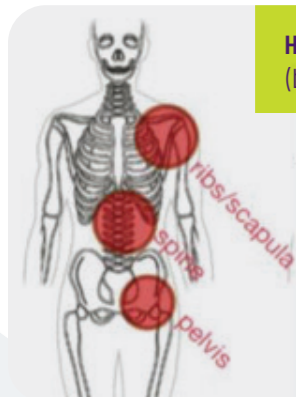


Diagnosis of mCSPC can occur either de novo or after relapse following local treatment¹

- The majority of mCSPC cases (75%) involve de novo disease presentation²
- The remaining 25% comprise of patients who have experienced relapse²

These distinct patient subgroups may experience varying benefits from different therapeutic approaches³

Disease can be defined as high or low risk and volume (defined below)⁴

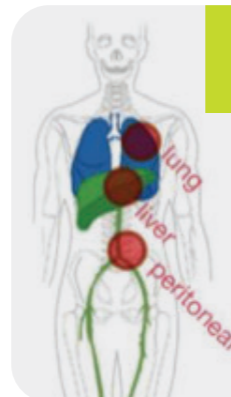


High-risk disease vs. low-risk disease⁵ (based on LATITUDE trial)

High-risk disease if ≥ 2 of the following features are present:

- ≥ 3 bone metastases
- visceral metastasis
- International Society of Urological Pathology grade ≥ 4

Low-risk disease: Not high risk



High-volume disease vs. low-volume disease⁶ (based on CHARTED trial)

High-volume disease if either of the following features are present:

- ≥ 4 bone metastases with ≥ 1 outside vertebral column and pelvis
- visceral metastasis

Low-volume disease: Not high volume

Management and therapy



- Mr V.G. was categorized as both high volume and high risk.
- He was given radiation and a doublet combination of Bicalutamide and androgen deprivation therapy (ADT).
- Apalutamide* (ERLEADA[®]) was added to his treatment regimen in February 2020.

*ERLEADA[®] is indicated in adult men for the treatment of mCSPC in combination with ADT.

The outcome



By May 2022:

- Mr V.G. exhibited a swift PSA response
- CT scans revealed the absence of new pulmonary or abdominal metastases
- The right parailiac lymph nodes returned to their normal size
- Previously identified osseous metastases remained nearly undetectable throughout the course of treatment.

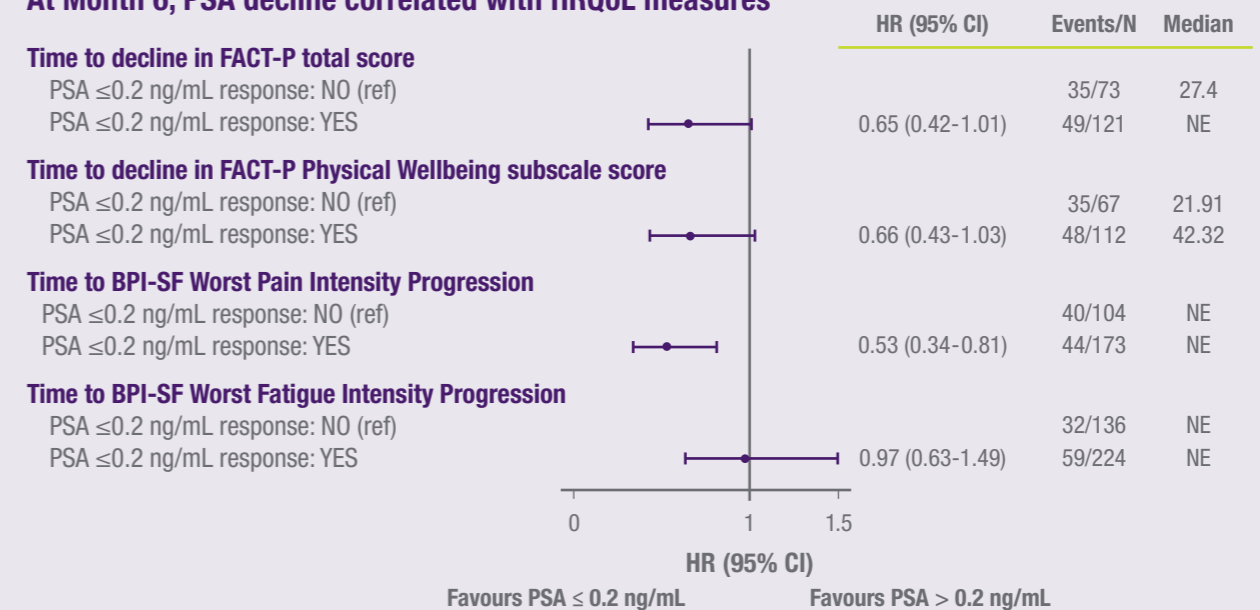


Treatment with ERLEADA[®] led to a swift and substantial fall in PSA

- The patient experienced a rapid and sustained PSA reduction, reaching ultra-low (UL) levels (≤ 0.2 ng/mL).
- These ultra-low levels were sustained at a 3-year follow-up.

The benefits of ERLEADA[®] go beyond overall survival. Patients who achieved PSA declines of ≤ 0.2 ng/mL preserved QoL for longer^{**^7}

At Month 6, PSA decline correlated with HRQoL measures



*Median treatment duration was 39.3 months; $>50\%$ of eligible patients completed FACT-P and $>62\%$ completed both BPI-SF and BFI (cycles 1-81) per assessment.⁷

^Compared to patients who did not achieve PSA ≤ 0.2 ng/mL

APA, apalutamide; BFI, Brief Fatigue Inventory; BPI-SF, Brief Pain Inventory-Short Form; CI, confidence interval; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HR, hazard ratio; HRQoL, health-related quality of life; mCSPC, metastatic castrate-sensitive; NE, not evaluable; PC, prostate cancer; PRO, patient-reported outcomes.

Mr. V. G.'s case highlights the potential of ERLEADA® as a viable treatment for patients living with mHSPC. The significant decrease in PSA levels, in combination with enhancements in bone metastases and overall quality of life, underscore the positive clinical outcomes associated with this androgen receptor inhibitor.⁸⁻¹⁰

ERLEADA® can benefit your mCSPC patients like Mr V.G.

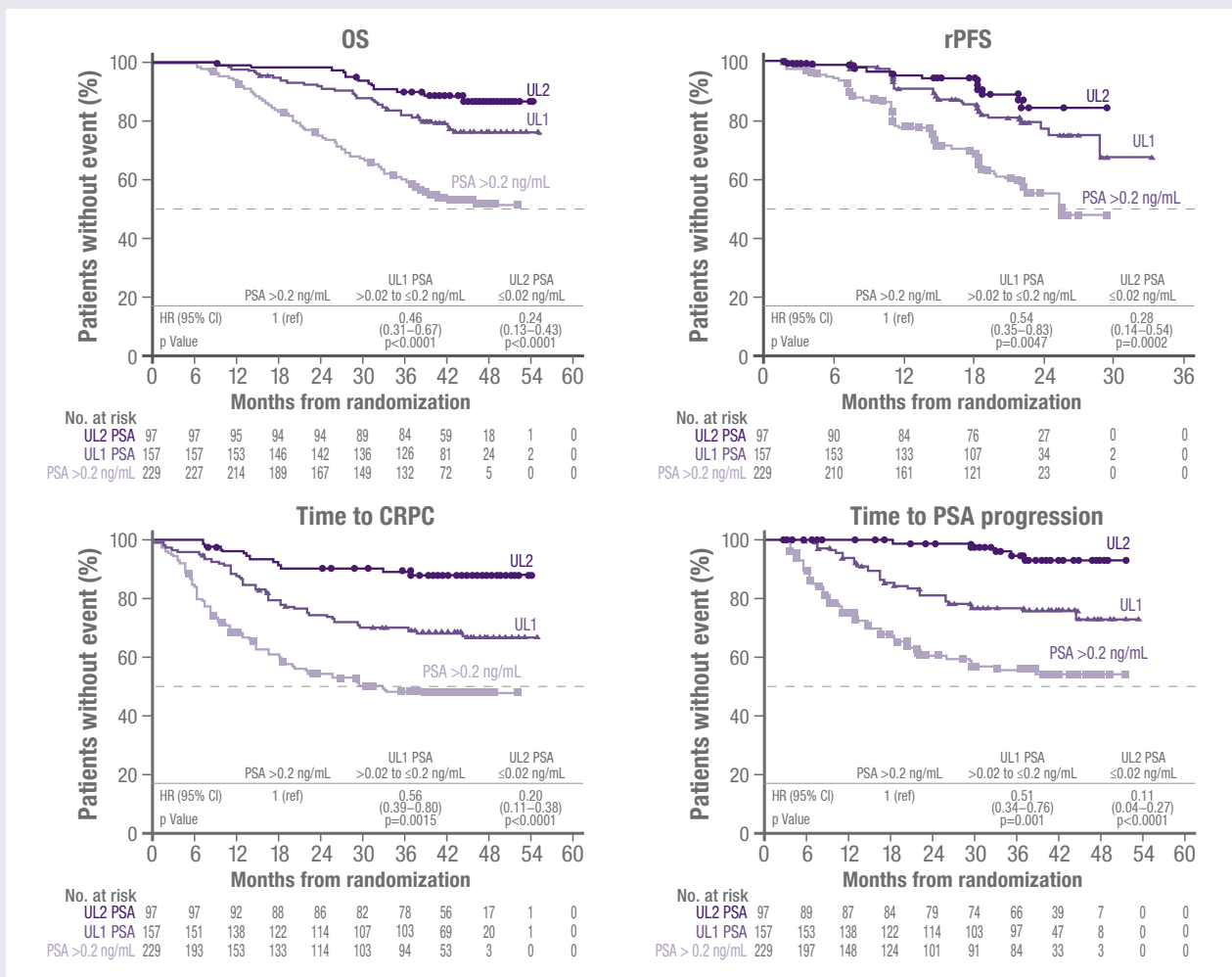


Substantially reduces PSA levels⁹



Improves bone metastases and overall quality of life¹⁰

ERLEADA® doublet therapy can significantly improve your patient's radiographic progression-free survival (rPFS)- regardless of patient volume and risk*⁸



ERLEADA® has demonstrated clinical benefits in various trials, improving both radiographic progression-free survival and overall survival. Furthermore, its favourable safety profile and ease of oral administration make it a strong choice for mHSPC patients.⁸⁻¹⁰

"Apalutamide has demonstrated clinical benefits in multiple trials, including improved radiographic progression-free survival and overall survival. Its favorable safety profile and oral administration make it a valuable option for patients with mHSPC"

- Professor Axel Merseburger

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