This promotional material has been developed and funded by Bayer plc and is intended for UK healthcare professionals only. NUBEQA® (darolutamide) is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy or with mHSPC in combination with docetaxel. **Prescribing information and adverse event reporting information can be found here and accessed via a QR code located at the bottom of the second page of this document.**

EXPLORING THE mHSPC PATIENT JOURNEY

MEET JOHN

SOCIAL HISTORY
- Retired engineer/fitter
- Ex-smoker, minimal alcohol

PAST MEDICAL HISTORY
- Diet-controlled type 2 diabetes
- Degenerative back pain
- Bronchiectasis

DRUG HISTORY
- Atorvastatin
- Morphine sulphate tablet
- Baclofen
- Fluoxetine

FAMILY HISTORY
- None

JANUARY 2020

- 60-years-old
- Referred by GP as 2WW with visible haematuria
- **PSA:** 68 µg/L
- **DRE:** hard right lobe
- **Gleason:** 3 + 4 = 7 on right and 3 + 5 = 8 on left
- **MRI:** T3b, 10mm right external iliac node
- **CT and bone scan:** -ve distant metastases
- **Staging:** T3bN1M0
- **Treatment:**
  - RT 60Gy in 20
  - 3 years of LHRHa

SEPTEMBER 2023

- **PSA:** 0.872 µg/L

[**prior PSA values:**
0.016 µg/L May 2023
0.012 µg/L Jan 2023
<0.007 µg/L Nov 2022]

FEBRUARY 2024

- Attended A&E with acute left sided loin to groin pain + blood on urinalysis
- **CT abdomen and pelvis:** para-aortic lymph nodes ≤15mm, enlarged pelvic lymph nodes, right common iliac nodes ≤ 3cm, 1 x liver lesion
- **Bone scan:** widespread bone disease
- **PSA:** 12 µg/L
- **Concomitant conditions:** type 2 diabetes, non-alcoholic fatty liver, obesity, depression
- **Concomitant medication:** nortriptyline, pregabalin, MST, metformin, dapagliflozin, tamsulosin, atorvastatin, baclofen, fluoxetine
- Started on Decapeptyl® with bicalutamide
- **High volume metachronous mHSPC**
- Pain poorly managed

This is a fictitious case study

RCT evidence supports triplet therapy as a treatment option for mHSPC

TREATMENT PARADIGM	OVERALL SURVIVAL (HR [95% CI], P VALUE)	INCIDENCE OF GRADE 3–4 AEs (%)
Triplet therapy		
NUBEQA + docetaxel + ADT vs docetaxel + ADT[1]	0.68 (0.57–0.80), p<0.001	66% (NUBEQA) vs 64% (placebo)
Triplet therapy – ARASENS subgroup analysis[2] NUBEQA + docetaxel + ADT vs docetaxel + ADT		
High risk disease‡	0.71 (0.58–0.86)	65% (NUBEQA) vs 64% (placebo)
High volume disease*	0.69 (0.57–0.82)	65% (NUBEQA) vs 64% (placebo)
Low risk disease‡	0.62 (0.42–0.90)	63% (NUBEQA) vs 62% (placebo)
Low volume disease*	0.68 (0.41–1.13)	70% (NUBEQA) vs 61% (placebo)

FOR MORE INFORMATION, SCAN THE QR CODE

*Disease volume defined by CHAARTED criteria; presence of visceral metastases or ≥4 bone metastases with ≥1 beyond vertebral bodies and pelvis
‡Disease risk defined by LATITUDE criteria (2 of the following three factors): Gleason score of ≥8, the presence of ≥3 bone lesions, or the presence of measurable visceral metastases

PP-NUB-GB-2329, June 2025

EXPLORING THE mHSPC PATIENT JOURNEY

NUBEQA + docetaxel + ADT extends survival and maintains QoL in mHSPC vs placebo + docetaxel + ADT[1–3]

<1% increase in AE incidence when NUBEQA is added to ADT and docetaxel[1,2]

RWE showed stable or improved QoL in 88% patients who received NUBEQA + docetaxel + ADT[3]

NUBEQA + docetaxel + ADT is recommended for patients with mHSPC who need treatment intensification[4]

UK consensus publication on the clinical utility of triplet therapy in patients with mHSPC[5]

Triplet therapy improves OS compared to ADT + docetaxel and **should be considered in all patients**, and **is recommended** (following assessment) in patients meeting ≥1 following criteria:

- ✓ Life expectancy severely limited by their cancer
- ✓ High risk or high volume disease
- ✓ Visceral disease
- ✓ Low volume disease with extra-pelvic lymph node involvement
- ✓ No/few comorbidities

EAU 2025 guidelines for the first-line treatment of mHSPC[4]

Offer **docetaxel only in combination with ADT plus abiraterone* or NUBEQA** to patients with **M1 disease and who are fit for docetaxel** (strong recommendation)

*Note that docetaxel + abiraterone + ADT is not licensed in the UK

NUBEQA + docetaxel + ADT demonstrated improved outcomes regardless of baseline PSA[6]

In ARASENS, the median baseline PSA was 30.3 ng/mL in the triplet arm and 24.2 ng/mL in the control arm.[1]

Regardless of baseline PSA levels, treatment with NUBEQA + docetaxel + ADT was associated with deep and durable PSA responses, including **higher rates of undetectable PSA** (<0.2 ng/mL) over time, **longer time to PSA progression**, and **longer time to CRPC progression** compared to placebo + docetaxel + ADT.[6]

OS and rates of AEs with NUBEQA + docetaxel + ADT are similar across the age spectrum in patients with mHSPC[7]

Post-hoc subgroup analysis of ARASENS trial data[7]

NUBEQA + docetaxel + ADT vs placebo + docetaxel + ADT

AGE SUBGROUP	N	OVERALL SURVIVAL (HR [95% CI]	INCIDENCE OF GRADE 3–4 AEs (%)
< 75 years	1086	0.70 [0.58–0.84]	65% (NUBEQA) vs 62% (placebo)
≥ 75 years	219	0.61 [0.41–0.91]	74% (NUBEQA) vs 70% (placebo)

FOR MORE INFORMATION, SCAN THE QR CODE

John received NUBEQA + docetaxel + ADT and benefitted from lower PSA, resolution of enlarged nodes/lesions and tolerated treatment well

April 2024

- Received **docetaxel 75 mg/m²** + NUBEQA PSA at baseline 16 µg/L

August 2024 (end of docetaxel)

- CT scan: enlarged nodes/liver lesions resolved, widespread sclerotic bone disease

December 2024

- PSA nadir 0.12 µg/L

January 2025

- CT scan: marginal deterioration of soft tissue component of sternal lesion

February 2025 (ongoing NUBEQA)

- PSA 0.38 µg/L

It is recommended to monitor patients for adverse reactions when NUBEQA is taken concomitantly with atorvastatin

Abbreviations. 2WW, two week wait (urgent suspected cancer referral); ADT, androgen deprivation therapy; AE, adverse event; A&E, accident and emergency; CRPC, castration resistant prostate cancer; CI, confidence interval; CT, computed tomography; DRE, digital rectal examination; EAU, European Association of Urology; GP, general practitioner; HR, hazard ratio; LHRHa, luteinizing hormone-releasing hormone analogue; mHSPC, metastatic hormone sensitive prostate cancer; MRI, magnetic resonance imaging; MST, morphine sulphate tablet; OS, overall survival; PSA, prostate specific antigen; QoL, quality of life; QR, quick response; RT, radiotherapy; UK, United Kingdom.

References. 1. Smith MR et al. N Engl J Med 2022;386(12):1132-42; 2. Hussain M et al. J Clin Oncol 2023;41(20):3595-607; 3. Bahl A et al, GU-ASCO 2025 Abstract 89; 4. EAU Guidelines on Prostate Cancer 2025; 5. Glen H et al. BMJ Open 2024;14:e090013; 6. Morgans A, et al. Presented at European Association of Urology; March 21–24, 2025; Madrid, Spain. Abstract A0512; 7. Carles J et al. ASCO GU 2025. Abstract 143.

Prescribing information and adverse event reporting information for NUBEQA®(darolutamide) is available via the QR code on the right. Either click here or scan the QR code for prescribing information and adverse event reporting information.

For direct access to this prescribing information, please ensure your device's browser settings have automatic PDF download enabled.