NUBEQA®
(darolutamide) 300 mg tablets

Prescribing Information and adverse event reporting information for NUBEQA® (darolutamide) can be accessed via the QR code located on the last page of this document.

CHOOSE NUBEQA® (DAROLUTAMIDE) IN YOUR PATIENT WITH mHSPC

NUBEQA 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 docetaxel.[1]

This promotional material has been organised and funded by Bayer and is intended for United Kingdom (UK) Healthcare Professionals (HCPs) only.

This material contains real patient case studies which have been anonymised. These are individual cases, experiences may vary.

PP-NUB-GB-2059 | DECEMBER 2024

ORION PHARMA

BAYER

TRIPLE THERAPY* PATIENT PROFILE

*Triple therapy consists of ADT + NUBEQA (darolutamide) + docetaxel

Eligibility for Nubeqa + ADT + Docetaxel[2,3]

- Newly diagnosed mHSPC
- Limited prior systemic treatment (≤12 weeks of ADT and not initiated upfront docetaxel chemotherapy for mHSPC)
- Performance status of 0 or 1
- Fit to tolerate chemotherapy – consider both chronological and biological age to assess overall fitness and treatment tolerance

EAU 2024 guidelines for the first-line treatment of hormone-sensitive metastatic disease:[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)

"When considering treatment options for patients with mHSPC, it is important to consider each patient individually, looking at their biological age, in addition to their chronological age. Patients who are fit enough to receive chemotherapy at the start of their treatment journey may benefit from early intensive triple therapy treatment with Nubeqa, ADT and docetaxel when they have fewer disease-related complications and comorbidities."

Dr Mark Prentice

"Treatment decisions should be personalised to each mHSPC patient. Clinical teams should incorporate the overall parameters of the metastatic disease in their shared decision making with the patient regarding the optimisation of treatment strategy. These patients may benefit from more intensive therapy based on fitness."

Professor Amit Bahl

Therapeutic goals for mHSPC patients beyond effective treatment:

- Minimise treatment-related AEs
- Maintain QoL that doesn't affect daily routines
- Minimise interactions with medications prescribed for common comorbidities
- Have treatment that they can remain on for an extended time

ADT, androgen deprivation therapy; AEs, adverse events; EAU, European Association of Urology; M1, metastasis 1; mHSPC, metastatic hormone sensitive prostate cancer; QoL, quality of life.

CASE STUDY 1

Provided by Dr Mark Prentice, consultant clinical oncologist, Royal Free London NHS Foundation Trust.

Phil: 77 years old male, referred via GP due to raised PSA in September 2023. Had previous stroke with complete recovery in December 2022 and has hypertension and minor coronary artery disease.

Phil's Medical history timeline

September 2023

Diagnosis of mHSPC

- PSA: 39.6 ng/mL
- Gleason score: 4+5 adenocarcinoma
- EGOC PS: 0
- Significant cardiovascular history
- Drug review: Atorvastatin switched to simvastatin for potential drug-drug interactions

September 2023

Initiation of ADT (Zoladex)

- PSA: 10 ng/mL (post-ADT initiation)

October 2023

Initiation of Nubeqa in combination with ADT

- PSA: 2 ng/mL (post-Nubeqa initiation)

November 2023

Initiation of docetaxel chemotherapy in combination with Nubeqa + ADT

- Grade 1 fatigue developed in cycles 4–5

May 2024

Completion of sixth cycle of docetaxel chemotherapy

- No treatment relays or dose reductions required
- PSA: <0.1 ng/mL

Nubeqa is suitable for patients with multiple comorbidities, like Phil, and has been shown to interact with fewer medications compared with other second generation ARIs.[1,5,6]

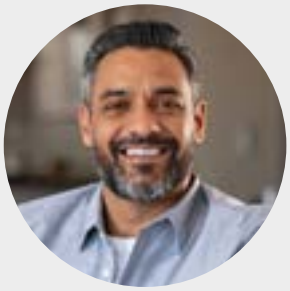
Phil's cardiovascular comorbidities were assessed prior to starting Nubeqa – his hypertension was controlled; a cardiovascular opinion was sought on the safety of triplet therapy prior to initiating treatment and a drug review was conducted. Patients with ischaemic heart disease should be monitored for signs and symptoms. Discontinue Nubeqa for Grade 3-4 ischaemic heart disease.

Phil suffered a previous stroke 9 months prior to his diagnosis of mHSPC, but triple therapy can still be initiated. The ARASENS trial showed that patients taking Nubeqa + ADT + docetaxel had similar rates of cerebral ischaemia compared to placebo + ADT.[3] Patients with clinically significant cardiovascular disease† in the past 6 months were excluded in the ARASENS study.[3] Therefore, the safety of Nubeqa in these patients has not been established. If Nubeqa is prescribed, patients with clinically significant cardiovascular disease should be treated for these conditions according to established guidelines.

ADT, androgen deprivation therapy; ARI, androgen receptor inhibitors; ECOG, Eastern Cooperative Oncology Group; GP, general practitioner; mHSPC, metastatic hormone sensitive prostate cancer; NHS, National Health Service; PS, performance status; PSA, prostate-specific antigen.
†Including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure.

CASE STUDY 2

Provided by Professor Amit Bahl, consultant clinical oncologist at Bristol Cancer Institute, University Hospitals Bristol.



Ian: 53 years old male with a history of hypertension and DVT and a family history of metastatic prostate cancer. Presented with urinary flow problems, erectile dysfunction and elevated PSA levels.

Ian's Medical history timeline

November 2022

Diagnosis of low-volume, low-risk de novo mHSPC

- Gleason score: 4+5
- MRI: T3b N0 Mx
- Bone Scan: Increased activity in L1 only
- CT Scan: 12mm suspicious lymph node
- MDT opinion recommend PSMA-PET scan
- Prior history of DVT and hypertension
- Drug review conducted for potential drug-drug interactions
- Initiation of ADT (Zoladex)

December 2022

Undergoes PSMA-PET Scan

- PSMA-PET: Highly avid locally invasive PC, widespread lymph node involvement, numerous skeletal metastases

February 2023

Initiation of docetaxel chemotherapy in combination with Nubeqa + ADT

- PSA: 4.0 ng/mL

May 2023

Completion of sixth cycle of docetaxel chemotherapy

- PSA: 0.5 ng/mL

June 2023

PSMA-PET scan: partial metabolic response in the primary tumour

- Undergoes radiotherapy
- PSA: 0.2 ng/mL

June 2024

Continues with ADT + Nubeqa therapy

- Maintains PSA: <0.003 ng/mL

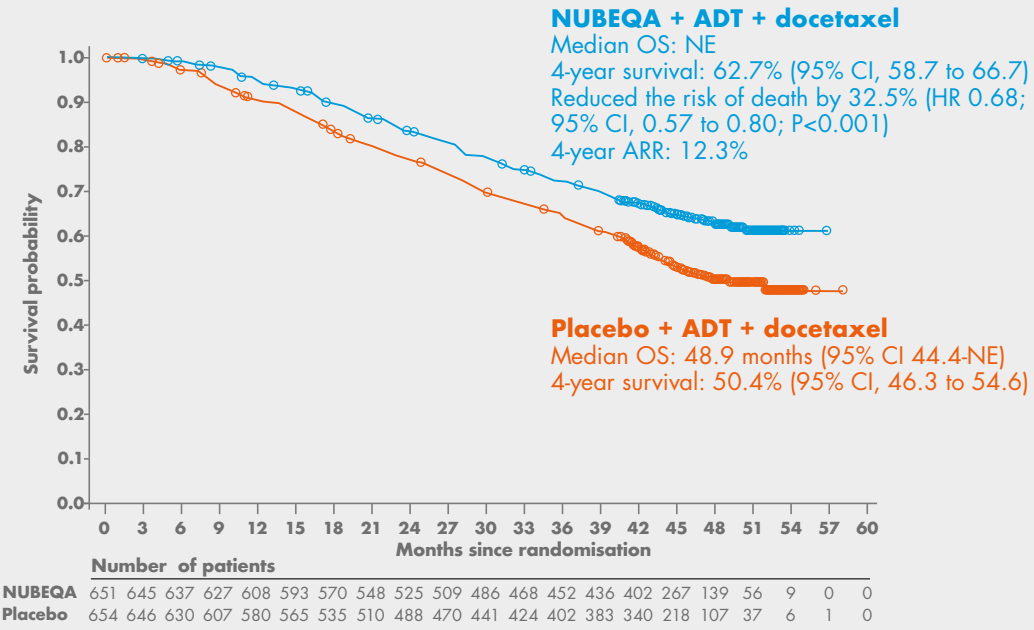
Nubeqa is suitable for patients with multiple comorbidities, like Ian, and has been shown to interact with fewer medications compared with other second generation ARIs.[1,5,6]

Ian's DVT and hypertension were evaluated and a drug review was conducted before initiating triple therapy with Nubeqa; treatment with atorvastatin was continued. Co-administration of NUBEQA may increase the plasma concentrations of atorvastatin. Therefore, Ian should be monitored for adverse reactions of atorvastatin.

ADT, androgen deprivation therapy; ARI, androgen receptor inhibitors; CT, computed tomography; DVT, deep vein thrombosis; MDT, multidisciplinary team; mHSPC, metastatic hormone sensitive prostate cancer; MRI, magnetic resonance imaging; PC, prostate cancer; PSA, prostate-specific antigen; PSMA-PET, prostate-specific membrane antigen positron emission tomography.

TRIPLE THERAPY WITH NUBEQA + ADT + DOCETAXEL SIGNIFICANTLY IMPROVES OS VS DOCETAXEL + ADT IN PATIENTS WITH mHSPC – ARASENS TRIAL[3]

ARASENS was a Phase III, double-blind trial evaluating the efficacy and safety of Nubeqa + ADT + docetaxel in mHSPC patients. Participants were randomised 1:1 to Nubeqa arm (n=651) or placebo arm (n=655). The primary endpoint was overall survival.



For Phil and Ian, treatment intensification with Nubeqa added to ADT and docetaxel can extend overall survival by >30% vs. ADT and docetaxel alone.[3]

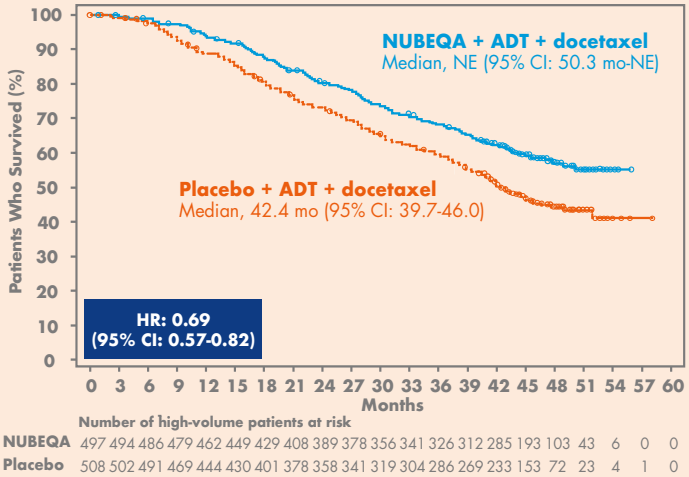
NUBEQA + ADT + DOCETAXEL IMPROVES OS IN HIGH-VOLUME AND HIGH/LOW-RISK mHSPC PATIENTS (ARASENS POST HOC ANALYSIS)[7*]

Nubeqa increased OS versus placebo + ADT + docetaxel in:

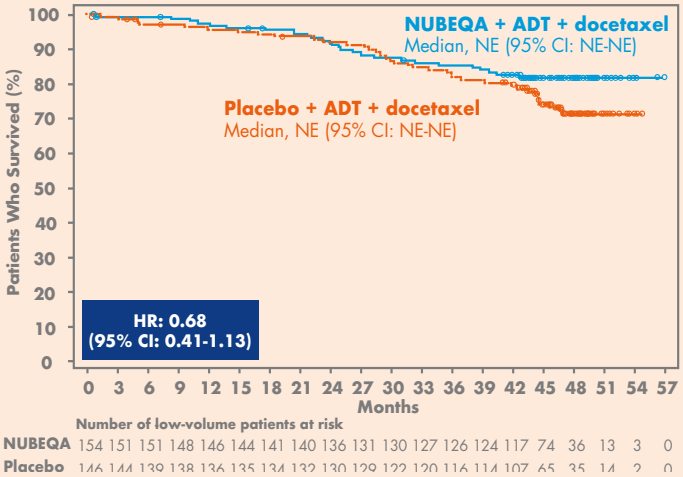
- High-risk patients (HR, 0.71; 95% CI, 0.58 to 0.86)
- Low-risk patients (HR, 0.62; 95% CI, 0.42 to 0.90)

The effect of NUBEQA treatment increased overall survival in patients with de novo and recurrent disease, and across subgroups of patients with high-volume, high-risk and low-risk disease. In the low-volume subgroup the results were also suggestive of survival benefit (HR, 0.68; 95% CI, 0.41 to 1.13); the small sample size in this sub-group may have contributed to the HR CIs crossing 1.0.

High-Volume
(NUBEQA, n=497; Placebo, n=508)



Low-Volume*
(NUBEQA, n=154; Placebo, n=146)

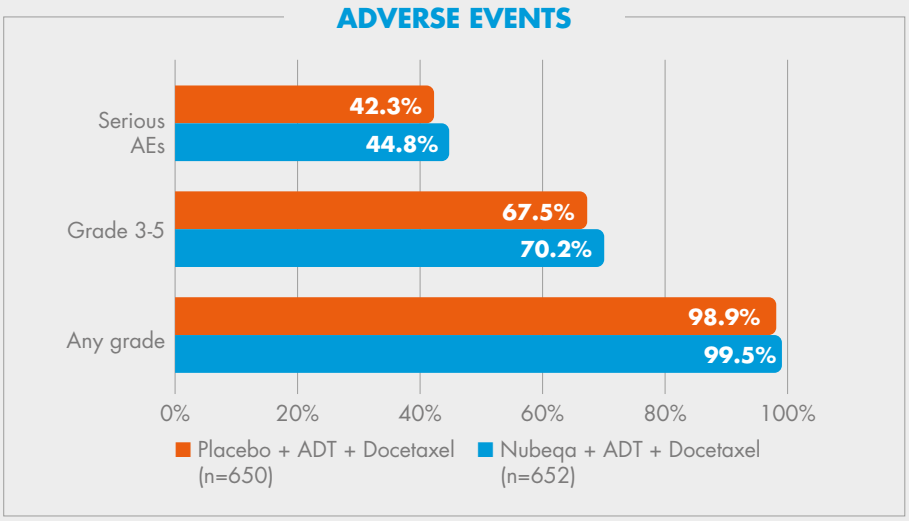


*High-volume disease was defined as visceral metastases and/or ≥ 4 bone metastases with ≥ 1 beyond the vertebral column/pelvis. High-risk disease was defined as ≥ 2 risk factors: Gleason score ≥ 8, ≥ 3 bone lesions, and presence of measurable visceral metastases.

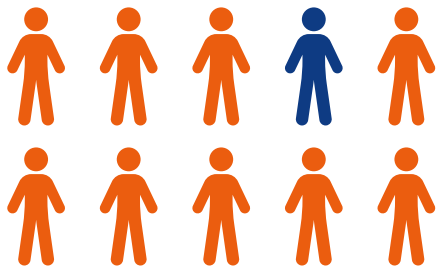
ADT, androgen deprivation therapy; ARR, absolute risk reduction; CI, confidence interval; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; mo, months; NE, not estimable; OS, overall survival.

IN ADDITION TO EXTENDING OS, NUBEQA HELPS mHSPC PATIENTS ACHIEVE THEIR THERAPEUTIC GOALS – ARASENS TRIAL[3]

MINIMISED ADDITIONAL AEs – Nubeqa resulted in <1% increase in AE incidence when added to ADT + docetaxel, despite longer treatment exposure (41 months) vs placebo + ADT + docetaxel (16.7 months)



The most common adverse reactions in patients receiving NUBEQA in combination with docetaxel were rash (17.3%) alanine aminotransferase (ALT) increased (15.8%), aspartate aminotransferase (AST) increased (14.0%) and hypertension (13.8%). The most common serious adverse reactions in patients receiving NUBEQA in combination with docetaxel were febrile neutropenia (6.1%), neutrophil count decreased (2.8%) and pneumonia (2.5%).[1]



CONTINUED TOLERABILITY - When Nubeqa was added to ADT and docetaxel, almost 9 out of 10 patients completed all six docetaxel cycles. The completion rates were high in both the Nubeqa group (87.6%) and the placebo group (85.5%).

After completing all docetaxel cycles, patients with mHSPC who received continued therapy with Nubeqa and ADT experienced a reduced incidence of AEs vs during docetaxel therapy.

After completing all docetaxel cycles, patients with mHSPC remained on treatment with Nubeqa and ADT longer than those on ADT + placebo (median 41.0 months vs 16.7 months)

41.0 months vs **16.7 months**

For patients with mHSPC like Phil and Ian, who often face high disease burden, treatment intensification with Nubeqa + ADT + docetaxel can improve OS and achieve therapeutic goals beyond effective treatment.[3]

ADT, androgen deprivation therapy; AEs, adverse events; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival.

CHOOSE NUBEQA IN YOUR PATIENTS WITH mHSPC

Nubeqa:

Extend survival

Offers a distinct molecular structure[8,9]

Maintain quality of life

Phil – The ARASENS trial shows Nubeqa is well tolerated in older patients (16.1% aged ≥75, n=105). Treatment plans should consider performance status and comorbidities, not just chronological age.[3] **When added to ADT and docetaxel, Nubeqa's proven tolerability allows elderly patients like Phil to stay on treatment, without further impacting their QoL and daily routines.**

Ian – ARASENS' post hoc analysis shows that Nubeqa + ADT + docetaxel improves OS in de novo patients with high-volume and high/low-risk mHSPC with a similar AE profile in the subgroups, consistent with the overall population.[7] **Patients like Ian with low-volume, low-risk de novo mHSPC along with multiple comorbidities can benefit from triple therapy with Nubeqa.**

Have you seen a patient in your clinic recently who could benefit from triple therapy with Nubeqa?

ADT, androgen deprivation therapy; AE, adverse event; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; QoL, quality of life.

REFERENCES:
1. NUBEQA (darolutamide) SmPC; 2. Cancer Drugs Fund list. https://www.england.nhs.uk/publication/national-cancer-drugs-fund-list (accessed December 2024); 3. Smith MR, et al. N Engl J Med. 2022 Mar 24;386(12):1132-1142; 4. EAU Guidelines on Prostate Cancer 2024. https://uroweb.org/guidelines/prostate-cancer (accessed December 2024); 5. XTANDI (enzalutamide) SmPC; 6. ERLEADA (apalutamide) SmPC; 7. Hussain M, et al. J Clin Oncol. 2023 Jul 10;41(20):3595-3607; 8. Zurth C, et al. J Clin Oncol. 2019;37:156; 9. Crawford ED, et al. Cancer Manag Res. 2020;12:5667–5676.

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