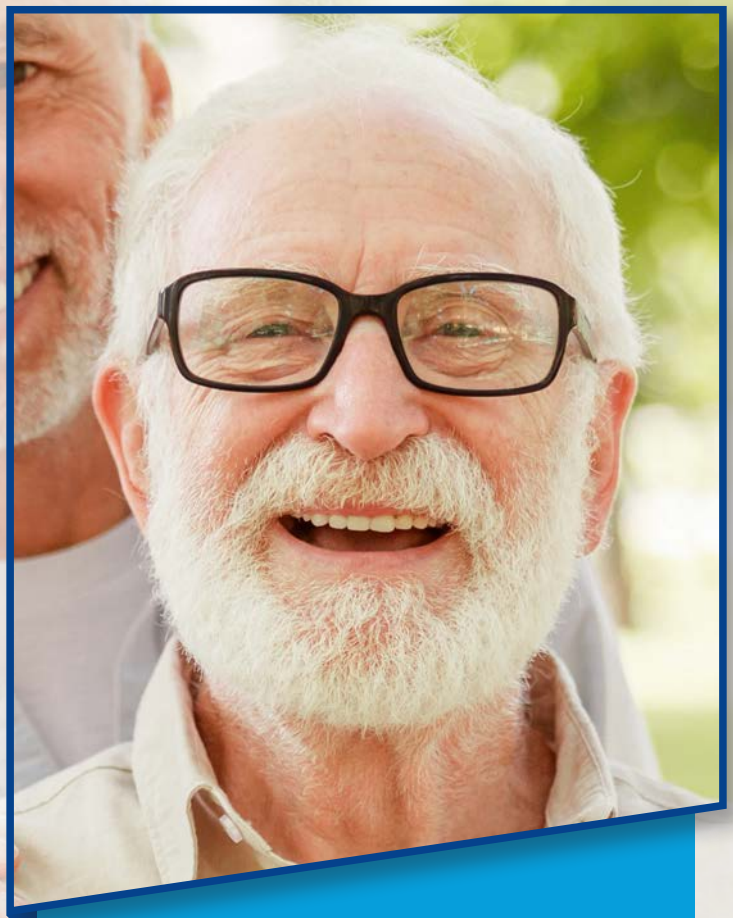


MEET THE PATIENT

A NUBEQA®(DAROLUTAMIDE) CASE STUDY

LISTEN & LEARN:
FOLLOW ALONG AS DR PARIKH PRESENTS THIS CASE STUDY

ORION PHARMA

NUBEQA® (darolutamide) 300 mg tablets

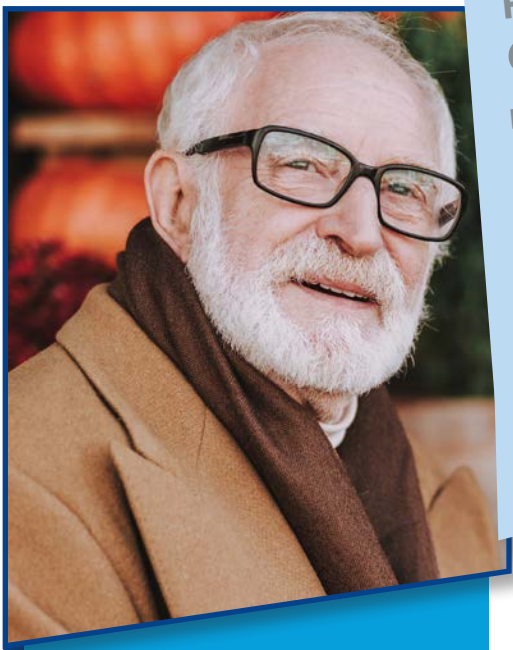
Prescribing information and adverse event reporting are available via the QR code or link on the last page.

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 UK HCPs only.

PP-NUB-GB-2045 | December 2024

BAYER



PATIENT CASE NOTES:

Diagnosis: April 2005

Norman presented with obstructive symptoms and underwent a TURP procedure. The MRI scan showed T4 cancer with bladder and rectal involvement and the bone scan showed no metastasis.

Treatment decision

Norman's care was transferred from Urology to Oncology. Due to co-morbidities, including hypertension, heart disease and a pacemaker, he was not offered radiotherapy.

MEET NORMAN[†]:

A retired fork-lift driver who lives with his wife and son. In his free time, Norman likes to spend time with his family.

TIME TO START NUBEQA*

*This patient was part of an extended access programme for NUBEQA

APRIL 2005

Underwent TURP procedure at 76 years old

Gleason score: 3+4 adenocarcinoma of prostate

PSA 8.5 ng/mL

Commenced ADT (zoladex)

FEBRUARY 2013

First PSA relapse

↑ PSA: 23.3 ng/mL

Commenced bicalutamide

MAY 2015

Second PSA relapse

↑ PSA: 31.4 ng/mL

Withdrew bicalutamide

MARCH 2020

Disease progressing

↑ PSA: > 50 ng/mL

Local symptoms: haematuria and renal impairment

Treatment: catherisation and dexamethasone.

[†]Photo and name are not of actual patient.

This is a real patient case study. This is an individual case, experiences may vary.

ADT, androgen deprivation therapy; ECOG PS, Eastern Cooperative Oncology Group performance status; MRI, magnetic resonance imaging; nmCRPC, non-metastatic castrate-resistant prostate cancer; PSA, prostate specific antigen; PSA-DT, prostate specific antigen doubling time; QoL, quality of life; TURP, transurethral resection of the prostate.

WHEN PSA CONTINUES TO RISE, CONSIDER NUBEQA®

Case study provided by Dr Omi Parikh

Dr Omi Parikh is a Consultant Clinical Oncologist at the Lancashire Teaching Hospitals NHS Foundation Trust and is Chair of the Lancashire & South Cumbria Urology Network Site Specific Group. Her interests include urological cancers and sarcoma. In the past 15 years, she has co-authored 19 peer reviewed articles and has expertise in prostate cancer, renal cell carcinoma, and chromophobe renal cell carcinoma.

Is your patient eligible for NUBEQA?[1]

Adult men with nmCRPC who are at high risk of developing metastatic disease may show the following signs:

- ☑ **No metastases detected in recent conventional imaging, pelvic lymph nodes up to 2 cm permissible**
- ☑ **Castration-resistant prostate carcinoma (testosterone <1.7 nmol/L PSA increase while on ADT, PSA ≥2 ng/ml)**
- ☑ **PSA doubling time of ≤10 months**

If your patient meets these criteria, they are at risk of developing metastatic disease.

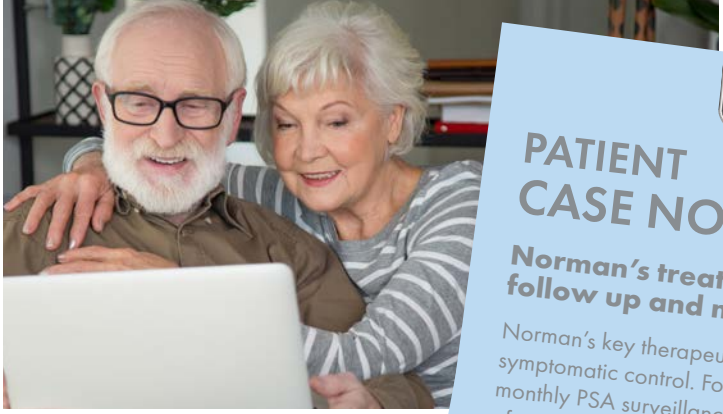
SEPTEMBER 2020

Progressive disease was diagnosed at 91 years old

- **PSA:** 82 ng/mL
- **PSA-DT:** 4.2 months
- **ECOG PS:** 1
- Not suitable for chemotherapy
- Non-metastatic disease
- **Initiated treatment with NUBEQA**

NORMAN'S TREATMENT GOALS:

- ☑ REDUCE SYMPTOMS
- ☑ MAINTAIN PATIENT QoL



PATIENT CASE NOTES:

Norman's treatment plan, follow up and monitoring.

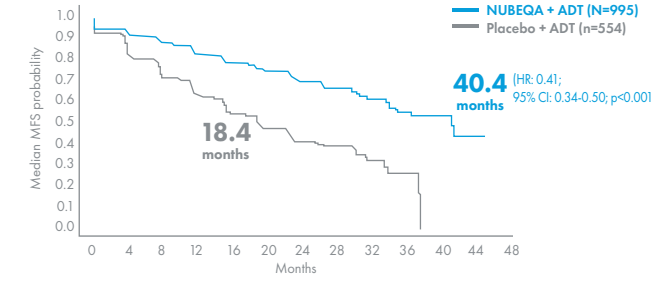
Norman's key therapeutic goal is symptomatic control. Follow up includes monthly PSA surveillance and monitoring of symptoms. No routine imaging is required.*

MARCH 2022

PSA: 3.2 ng/mL

NUBEQA MAY HELP YOU DELIVER ON WHAT'S IMPORTANT TO PEOPLE WITH HIGH-RISK nmCRPC

NUBEQA HAS BEEN SHOWN TO EXTEND MFS[2]:



No. at risk

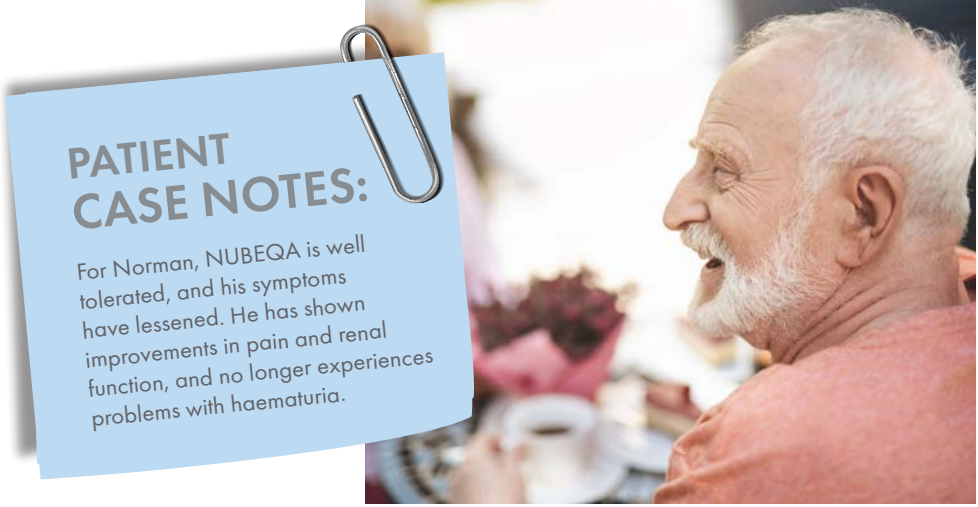
NUBEQA	955	817	675	506	377	262	189	116	68	37	18	2	0
Placebo	554	368	275	180	117	75	50	29	12	4	0	0	0

Adopted from Fizazi *et al.* 2019

40 months MFS: more than double the median MFS with NUBEQA + ADT vs ADT + placebo[2]

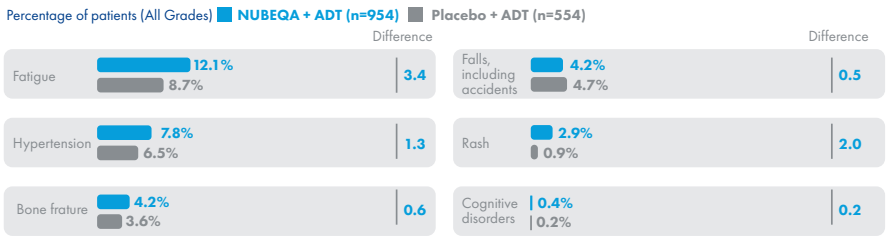
NUBEQA + ADT demonstrated 31% reduced risk of death vs placebo + ADT in high-risk nmCRPC

ARAMIS is a multinational, randomised,double-blind, placebo-controlled Phase 3 trial investigating the safety profile and efficacy of darolutamide in patients with nmCRPC[1]



IN ARAMIS, NUBEQA + ADT SHOWS A GENERALLY ACCEPTABLE TOLERABILITY PROFILE AND LOW DISCONTINUATION RATE VS PLACEBO + ADT[2,3]

AEs of concern to people with high-risk nmCRPC with NUBEQA + ADT and placebo + ADT[2,3]



8.9% vs 8.7% OF PATIENTS DICONTINUED DUE TO AES ON NUBEQA + ADT VS PLACEBO + ADT, RESPECTIVELY[3,4]

THE CLINICAL BENEFIT OF NUBEQA + ADT HAS BEEN SHOWN TO EXTEND SEVERAL YEARS VS PLACEBO + ADT[3]

30.1% OF PATIENTS RECIEVED NUBEQA FOR ≥ 4 YEARS[3]

This is an individual case, experiences may vary.

ADT, androgen deprivation therapy; AE, adverse event; CI, confidence internal, DB, double-blind; HR, hazard ratio; MFS, metastasis-free survival; nmCRPC, non-metastatic castration-resistant prostate cancer; OL, open-label; OS, overall survival, PSA, prostate specific antigen; ROS, rollover study.

*Radiological imaging may be considered if clinically appropriate for disease progression.

† ARAMIS trial. Men with high-risk nmCRPC. NUBEQA + ADT (n=955) vs. placebo + ADT (n=554). Primary endpoint was MFS.

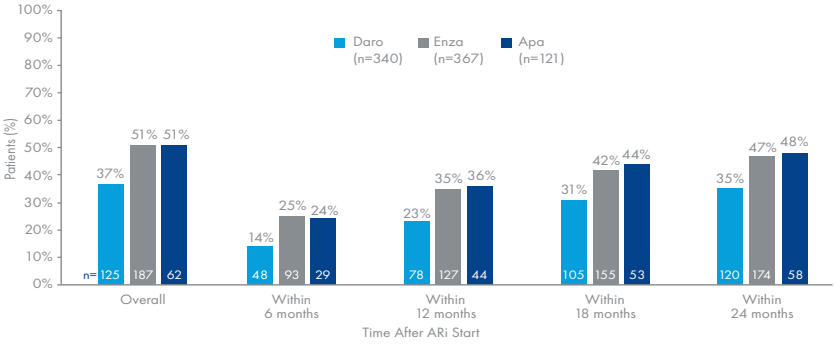
PATIENT CASE NOTES:

Since starting NUBEQA, Norman has experienced an improvement in his symptoms and overall QoL. He has no recorded toxicities and had no dose reductions since commencing treatment.

NUBEQA HAS SHOWN LOW RATES OF DISCONTINUATION IN A REAL-WORLD SETTING[5]

The DEAR study: Use of Darolutamide, Enzalutamide and Apalutamide in the Real World for nmCRPC, presented at ASCO GU 2023

The DEAR study was a retrospective, observational chart review study using electronic medical records from the Precision Point Specialty network of US urology practices. The DEAR study was not a head-to-head trial. All patients had nmCRPC, and the primary endpoint was a composite of the time to initial ARi discontinuation or progression to mCRPC[5].



Median time to discontinuation/progression to mCRPC (95% CI)

NUBEQA	Enzalutamide	Apalutamide
Not reached (30.1, NA)	23.1 (18.2, 26.4)	20.5 (12.3, 27.2)

THE DEAR STUDY[5]

- Enhances our knowledge of nmCRPC management in the real-world setting
- Supports the low discontinuation rate for NUBEQA seen in ARAMIS (rates of discontinuation due to AE: 8.9% in ARAMIS vs. 9.7% in DEAR)

Don't let the learning stop here. Access the latest on prostate cancer and Nubeqa® on our Hub, including podcasts, on demand webinars and other educational resources.

SCAN HERE

This is an individual case, experiences may vary.

ADT, androgen deprivation therapy; AE, adverse event; ARi, androgen receptor inhibitor; CI, confidence internal, NA, not available; HR, hazard ratio; mCRPC, metastatic castration-resistant prostate cancer; QoL, quality of life; SmPC, summary of product characteristics.

HELP HIM LIVE FOR WHAT HE LOVES.

THINK NUBEQA[1-5]

MEDIAN METASTASIS-FREE SURVIVAL

22 MONTHS
longer MFS vs. placebo + ADT[2]

(40.4 months vs. 18.4 months, HR: 0.41; 95% CI: 0.34–0.50; p<0.001)

DISCONTINUATION RATES

Similar rates of discontinuation of treatment due to adverse events vs. placebo + ADT[2]

(Rate of treatment discontinuation: 8.9% vs. 8.7%)[3,4]

ADVERSE EVENTS

Incidence of AEs of concern vs. placebo + ADT[3]

(Fatigue (13.2% vs. 8.3%); Bone fracture (5.5% vs. 3.6%); falls, including accident (5.2% vs. 4.9%); cognitive disorders (2.0% vs. 1.8%); rash (3.1% vs. 1.1%)

BAYER

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.

References: 1. NUBEQA (darolutmaide) SmPC. 2. Fizazi K et al. N Engl J Med. 2019;380(13):1235–1246. 3. Fizazi K et al. N Engl J Med. 2020;383:1040–1049. 4. Shore N. et al. ASCO 2023. Abstract #147. 5. George DJ, et al. ASCO GU. 2023. Poster Presentation 332.