From congresses to local practice: data updates from 2026 congresses

NUBEQA (darolutamide) relevant updates – ASCO-GU 2026

Prescribing information and adverse event reporting information for NUBEQA (darolutamide) is available at the end of this presentation.

This promotional summary resource has been organised and fully funded by Bayer PLC. Bayer products are discussed. This resource is intended for UK Healthcare Professionals only.

PP-NUB-GB-2968 | March 2026

Adverse event reporting information

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel: 0118 206 3500 Email: pvuk@bayer.com.

Further information is available on the “contact” tab at www.bayer.co.uk

Quick recap: NUBEQA (darolutamide) has three Phase 3 studies resulting in three indications in mHSPC and nmCRPC[1-4]

All three indications are NICE recommended[5-7]

ARAMIS[3]	ARASENS[2]	ARANOTE[4]
Darolutamide + ADT in high-risk nmCRPC	**Darolutamide + ADT + Docetaxel in mHSPC**	**Darolutamide + ADT in mHSPC**
Delayed tumour progression by 22 months Reduced the risk of death by >30%[c] vs. ADT + Placebo *Absolute risk reduction at 3 years, 5.7%*	Extended overall survival by >30% vs ADT + Docetaxel + Placebo *Absolute risk reduction at 4 years, 12.3%*	Reduced the risk of radiographic progression or death by 46% vs ADT + Placebo *Absolute risk reduction at 2 years, 18.2%*

2019 → 2022 → 2025

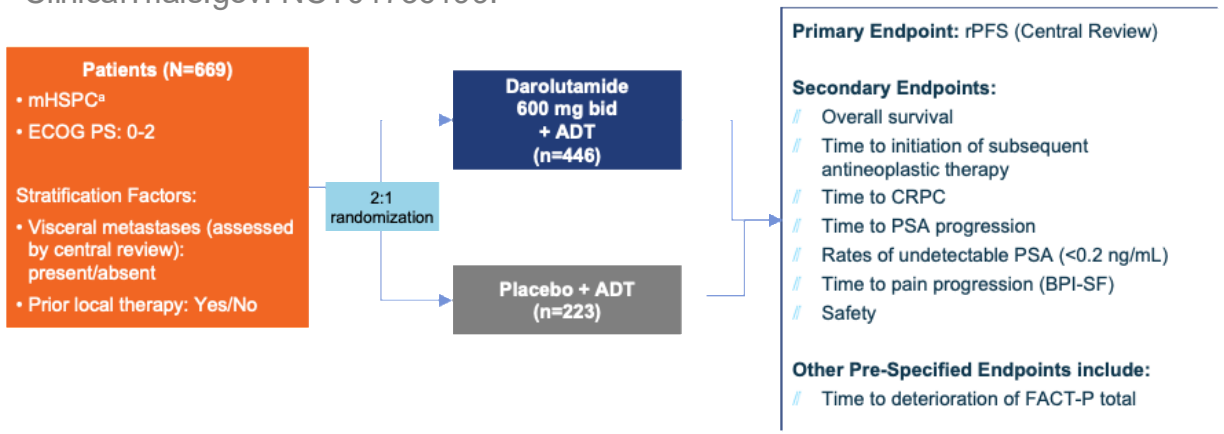
*the eligibility criteria for treatment with Darolutamide for patients with high-risk nmCRPC is: no metastases detected in conventional imaging, pelvic lymph nodes up to 2 cm permissible; Castration-resistant prostate carcinoma (testosterone <1.7 nmol/L PSA increase while on ADT, PSA ≥ 2ng/ml); PSA doubling time of ≤ 10 months (this list is not exhaustive)[4]

1. NUBEQA (Darolutamide) Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/product/11324/smpc (Accessed March 2026). 2. Smith M, et al. *N Engl J Med*. 2022;386(12) 3. Fizazi K *et al*. N Engl J Med. 2019;380(13)1235-1246. 4.Saad, F, et al. J Clin Oncol. 2024;42(36);4271-81. 5. NICE. TA903.2023. 6 . NICE. TA660. 2020. 7. NICE. TA1109. 2025

Quick recap: ARANOTE [1-2]

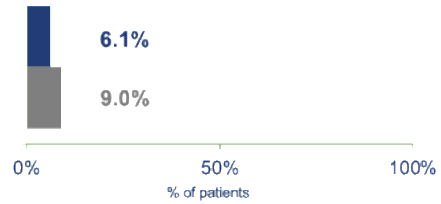
Trial Design:

ClinicalTrials.gov: NCT04736199.



TEAE, no. of patients (%) [1]	Darolutamide + ADT (n=445[a])[1]	Placebo + ADT (n=221[a]) [1]
Any AE	405 (91.0)	199 (90.0)
Serious AE	105 (23.6)	52 (23.5)
Grade 3 or 4 AE	137 (30.8)	67 (30.3)
Grade 5 AE	21 (4.7)	12 (5.4)

TEAEs Leading to Permanent Discontinuation of Darolutamide/Placebo[1]



- The ARANOTE study's primary endpoint is rPFS, clinically accepted for efficient evaluation of treatment effectiveness.[1,3,4]
- **PRIMARY ENDPOINT**: NUBEQA (darolutamide) + ADT significantly reduced the risk of radiographic progression or death by 46%* (absolute risk reduction at 2 years:18.2%; HR: 0.54; 95% CI: 0.41–0.71; p<0.0001).[1]
- NUBEQA (darolutamide) is the only 2nd generation ARI in mHSPC with lower levels of fatigue and fewer discontinuations versus placebo when added to ADT in a Phase 3 clinical trial[1,5,6]

ARANOTE is a randomised, double-blind, placebo-controlled, Phase III trial involving patients with mHSPC. Patients (N=669) were randomly assigned in a 2:1 ratio to receive NUBEQA + ADT (n=446) or placebo + ADT + docetaxel (n=223) The primary endpoint was rPFS. The rPFS rates at 24 months were 70.3% in the NUBEQA + ADT group and 52.1% in the placebo + ADT group.[1] In the pooled analysis of ARAMIS and ARANOTE, the most common adverse reactions in patients receiving NUBEQA were fatigue/asthenic conditions (13.7%).[2] The most common serious adverse reactions were ischaemic heart disease (1.9%), cardiac arrhythmias (1.8%), pneumonia (1.5%),urinary retention (1.3%), urinary tract infection (1.1%) and fractures (1.0%).[2]

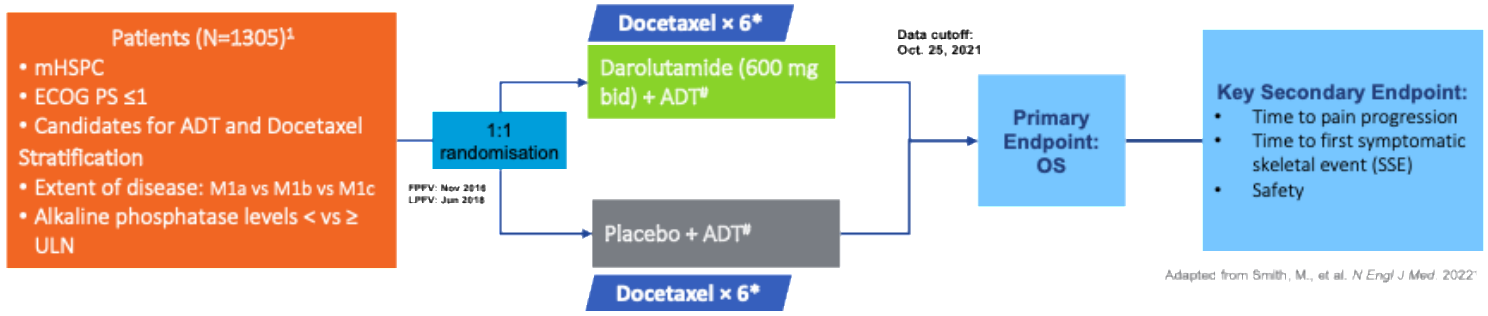
CRPC, castration resistant prostate cancer; rPFS, radiographic progression free survival

1. Saad F, et al. *J Clin Oncol.* 2024. doi:10.1200/JCO-24-01798 . 2. NUBEQA® (darolutamide) UK Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc#gref (Accessed: March 2026) . 3. Halabi S, et al. *J Clin Oncol* DOI:10.1200/JCO.23.01535 4. Shore et. Al doi.: 10.1016/j.ejca.2025.115513 5. enzalutamide SmPC. Available at: https://www.medicines.org.uk/emc/product/10318/smpc. [Accessed March 2026]. 6. ERLEADA®(apalutamide) SmPC. Available at: https://www.medicines.org.uk/emc/product/9832/smpc. [Accessed March 2026].

Quick recap: ARASENS[1-2]

Trial Design:

ClinicalTrials.gov: NCT02799602



Adapted from Smith, M., et al. *N Engl J Med*. 2022

‡ The primary analysis was conducted after 533 deaths

‡ Secondary efficacy endpoints were tested hierarchically

- For patients with mHSPC, who face an increased disease burden and require intensified treatment:
  - Darolutamide significantly extended survival and reduced the risk of death by >30% when added to ADT and docetaxel (absolute risk reduction at 4 years: 12.3%; HR: 0.68; 95% CI: 0.57–0.80; p<0.0001) [1, 3]
- When added to ADT and Docetaxel, Darolutamide's proven tolerability allowed patients to stay on treatment, without further impacting their QoL and daily routines
  - Less than 1% increase in any AE incidence when added to ADT and Docetaxel[1]
  - When Darolutamide was added to ADT and Docetaxel, almost 9 out of 10 patients completed all 6 Docetaxel cycles[1]

ARASENS trial. Men with mHSPC. NUBEQA + ADT + docetaxel (n=651) vs placebo + ADT + docetaxel (n=654). Primary endpoint was OS. 32.5% reduction in risk of death vs placebo + ADT + docetaxel (HR: 0.68; 95% CI: 0.57-0.80; p<0.0001). Median OS: NE months vs 48.9 months with placebo + ADT + docetaxel. Number of patients with events 229/651 (35.2%) vs 304/654 (46.5%) with placebo + ADT + docetaxel. Docetaxel 75 mg/m2 q3w x 6 cycles.[1] The most common AEs in mHSPC patients receiving NUBEQA in combination with docetaxel were rash (17.3%), ALT increased (15.8%), AST increased (14.0%) and hypertension (13.8%).[4] The most common SAEs in mHSPC patients receiving NUBEQA in combination with docetaxel were febrile neutropenia (6.1%), neutrophil count decreased (2.8%) and pneumonia (2.5%).[4] Discontinuation rates due to AEs: 13.7% NUBEQA + ADT + docetaxel vs 10.6% placebo + ADT + docetaxel.[1,4]

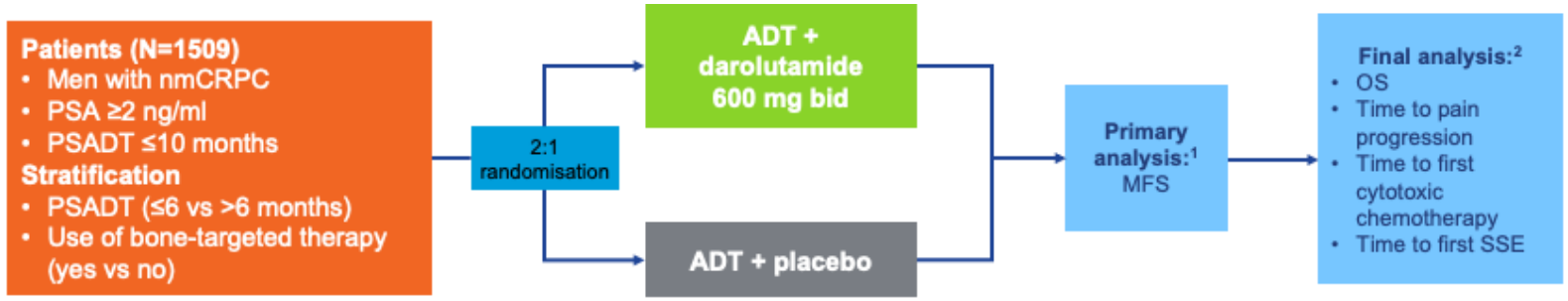
*Starting ≤6 weeks after start of study drug at 75 mg/m^2 / 3 weeks, 6 cycles (in combination with prednisone/prednisolone at the discretion of the investigator).
#Investigators' choice (including orchiectomy) starting ≤12 weeks before randomisation
†One enrolled patient was excluded from all analysis sets because of Good Clinical Practice violations.
‡One patient randomised to the Placebo group but who received Darolutamide was included in the Placebo group for the full analysis set and in the Darolutamide group for the safety analysis set.
ADT, androgen deprivation therapy; BID, twice daily; ECOG, Eastern Cooperative Oncology Group; FPFV, first-patient first-visit; LPFV, last-patient first-visit; mHSPC, metastatic hormone-sensitive prostate cancer; ULN, upper limit of normal.

1. Smith, M., et al. *N Engl J Med*. 2022; 386: 1132-1142. 2. ClinicalTrials.gov identifier NCT02799602. https://clinicaltrials.gov/ct2/show/NCT02799602. [Accessed March 2026]. 3. Hussain, M., et al. J Clin Oncol. 2023; JCO2300041. 4. NUBEQA® (darolutamide) UK Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc#gref (Accessed: March 2026)

Quick recap: ARAMIS[1-2]

Trial Design:

ClinicalTrials.gov: NCT02200614



Primary endpoint

- MFS
  - Defined as time from randomisation to confirmed evidence of distant metastases or death from any cause (whichever occurred first)
  - Radiological assessment at 16-week intervals
  - Any patients with baseline metastases identified by independent central efficacy review were included as a baseline event

Secondary endpoints

- OS
- Time to pain progression
- Time to first cytotoxic chemotherapy
- Time to first SSE

Adapted from Fizazi K et al. *N Engl J Med* 2019[1]

- In ARAMIS, darolutamide + ADT significantly delayed tumour progression, extended survival and reduced the risk of death by >30%* vs placebo + ADT
  - *absolute risk reduction at 3 years: 5.7%; HR: 0.69; 95% CI: 0.53–0.88; p=0.003.[1-2]
- When added to ADT, darolutamide's proven tolerability helped nmCRPC patients continue treatment, without further impacting their QoL and daily routines vs placebo + ADT.
  - The only 2nd generation ARI with <1% increase in treatment discontinuation when added to ADT in a Phase 3 clinical trial in nmCRPC.[1-4]

ARAMIS trial. Men with high-risk nmCRPC. NUBEQA + ADT (n=955) vs placebo + ADT (n=554). Primary endpoint was median MFS. Median MFS for NUBEQA + ADT was 40.4 months (n=955) vs 18.4 months for placebo + ADT (n=554). Absolute risk reduction for MFS at 2 years is 28.3% (HR: 0.41; 95% CI: 0.34–0.50; p<0.000001). Secondary endpoint was OS. 31% reduction in risk of death vs ADT alone. Absolute risk reduction at 3 years, 5.7%, HR: 0.69; 95% CI: 0.53-0.88; p=0.003. OS for NUBEQA + ADT was NR (95% CI: 56.1-NR) vs NR (95% CI: 46.9-NR) for placebo + ADT (HR: 0.69 (95% CI: 0.53-0.88), p=0.003). Number of patients with OS events 148/955 (15.5%) vs 106/554 (19.1%) with placebo + ADT. Final analysis for OS was conducted after 254 deaths. [2] Safety was evaluated in all patients who underwent randomisation and received at least one dose of darolutamide or placebo. In the pooled analysis of ARAMIS and ARANOTE, the most common adverse reactions in patients receiving NUBEQA were fatigue/asthenic conditions (13.7%).[5] The most common serious adverse reactions were ischaemic heart disease (1.9%), cardiac arrhythmias (1.8%), pneumonia (1.5%), urinary retention (1.3%), urinary tract infection (1.1%) and fractures (1.0%).[5] Discontinuation rates due to AEs: 8.9% NUBEQA + ADT vs 8.7% placebo + ADT (nmCRPC).[5]

ADT, androgen deprivation therapy; bid, twice daily; MFS, metastasis-free survival; nmCRPC, non-metastatic castration-resistant prostate cancer; OS, overall survival; PSADT, prostate-specific antigen doubling time; SSE, symptomatic skeletal event.

1. Fizazi K et al. *N Engl J Med* 2019;380:1235–1246; 2. Fizazi K et al. *N Engl J Med* 2020;383:1040–1049. 3. Hussain M, et al. N Engl J Med. 2018;378(26)2465–2474; 4. Smith MR, et al. N Engl J Med. 2018. 378;15:1408–1418; 5. NUBEQA® (darolutamide) UK Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc#gref (Accessed: March 2026)

ASCO-GU 2026

February 26-28th

Impact of hospitalisations on HRQoL and OS in mHSPC: insights from the ARANOTE trial

Objective

To evaluate the impact of hospitalisations on HRQoL and OS in patients with mHSPC, using data from the ARANOTE trial

Key result: HRQoL

Baseline pain and TEAE-related hospitalisations were associated with FACT-P declines of −16.09 and −6.14 points, respectively

This met or exceeded the 6–10-point MCID, which indicated a clinically meaningful HRQoL deterioration

GEE mixed model regression results using FACT-P total scores

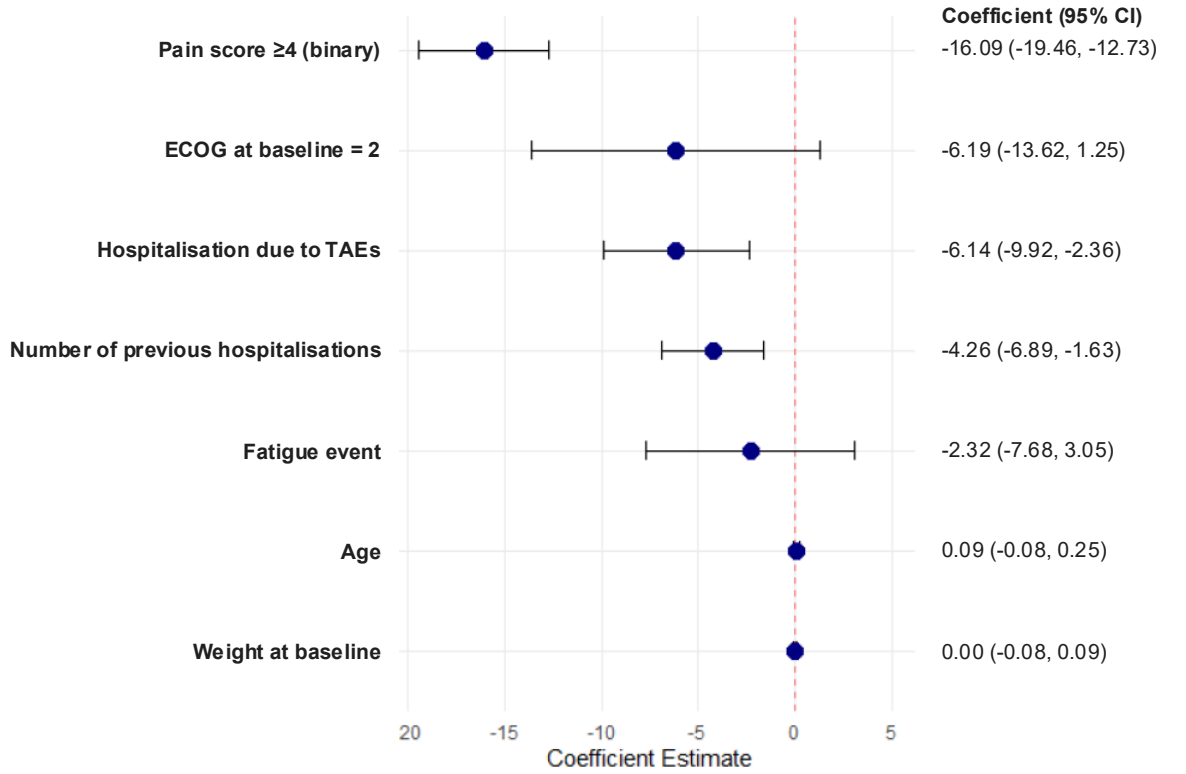


Figure adapted from Morgans A, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 53.

HRQoL was assessed via FACT-P. Covariates for HRQoL included number of prior all-cause hospitalisations, hospitalisations due to treatment-related AEs, baseline pain scores (<4 vs ≥4), baseline ECOG performance status score (0–1 vs 2), grade of fatigue (any grade AE during participation in the trial), baseline age and baseline weight. OS was evaluated using time-varying Cox proportional hazards regression. Covariates for the OS model included treatment, TEAEs and number of prior all-cause hospitalisations.

AE, adverse event; CI, confidence interval; HRQoL, health-related quality of life; ECOG, Eastern Cooperative Oncology Group; FACT-P, functional assessment of cancer therapy–prostate; GEE, generalised estimating equations; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; TEAE, treatment-emergent adverse event; MCID, minimal clinically important difference.

Morgans A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 53.

Impact of hospitalisations on HRQoL and OS in mHSPC: insights from the ARANOTE trial

Summary

- Prior hospitalisations and baseline pain were consistent determinants of reduced HRQoL, with baseline pain as the strongest driver of HRQoL decline among men with mHSPC
- Each additional previous hospitalisation for any reason was associated with a significantly increased hazard of death (HR 1.52; 95% CI 1.39–1.66; p<0.0001)
- Taken together, these findings suggest that well-tolerated treatments may support sustained quality of life and survival by avoiding additional hospitalisation burden

Author's conclusions: Prior all-cause hospitalisations were linked to poorer survival and HRQoL, highlighting the need for well tolerated treatments and the importance of proactively managing symptom burden and comorbidities to reduce the need for hospitalisations and maintain quality of life

CI, confidence interval; HR, hazard ratio; HRQoL, health-related quality of life; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival.

Morgans A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 53.

Efficacy and safety of darolutamide and ADT in patient subgroups by baseline comorbidities and concomitant medications: ARANOTE post-hoc analyses

Objective

To report outcomes in patients with mHSPC treated with darolutamide plus ADT or placebo plus ADT, by comorbidities and concomitant medications at baseline, using data from the ARANOTE trial

Key result: rPFS by comorbidities and concomitant medications

The rPFS benefit of darolutamide plus ADT versus placebo plus ADT was consistent across comorbidity and concomitant medications subgroups

rPFS by comorbidities and concomitant medications

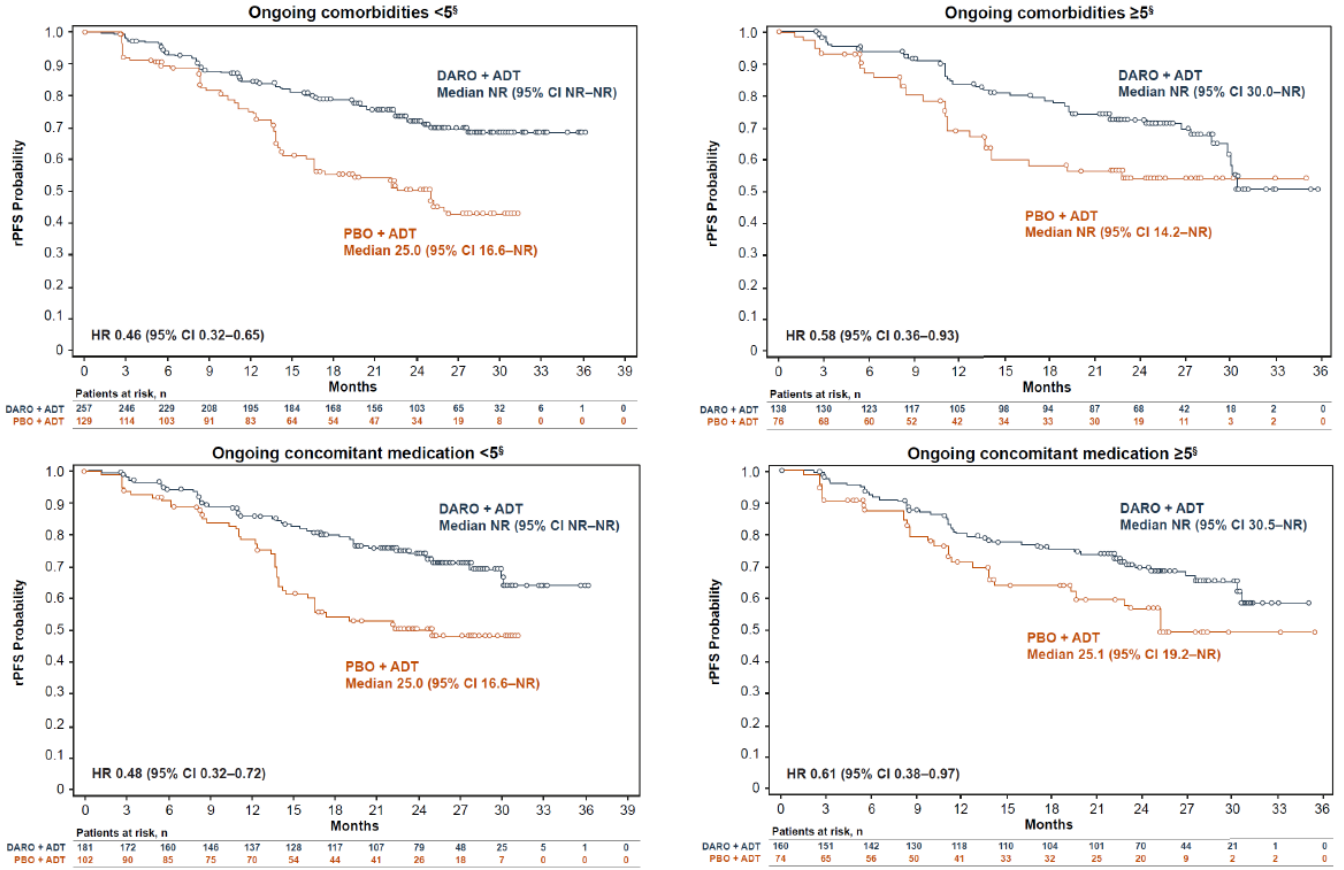


Figure adapted from Saad F, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 178.

Analysis used the ConcertAI Patient360 database. Patients were randomised 2:1 to darolutamide 600 mg orally twice daily or placebo, both with ADT. Patients were grouped by median number and type of comorbidities or concomitant medications reported at baseline. A post-hoc analysis was conducted for rPFS and hazard ratios were estimated using a Cox regression model.

ADT, androgen deprivation therapy; CI, confidence interval; DARO, darolutamide; mHSPC, metastatic hormone-sensitive prostate cancer; PBO, placebo; rPFS, radiological progression-free survival.

Saad F, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 178.

Efficacy and safety of darolutamide and ADT in patient subgroups by baseline comorbidities and concomitant medications: ARANOTE post-hoc analyses

Key result: rPFS by comorbidity type

Darolutamide plus ADT showed a consistent rPFS benefit compared with placebo plus ADT, including in patients with or without metabolic, cardiovascular, renal or urinary, gastrointestinal and musculoskeletal disorders

rPFS by comorbidity type

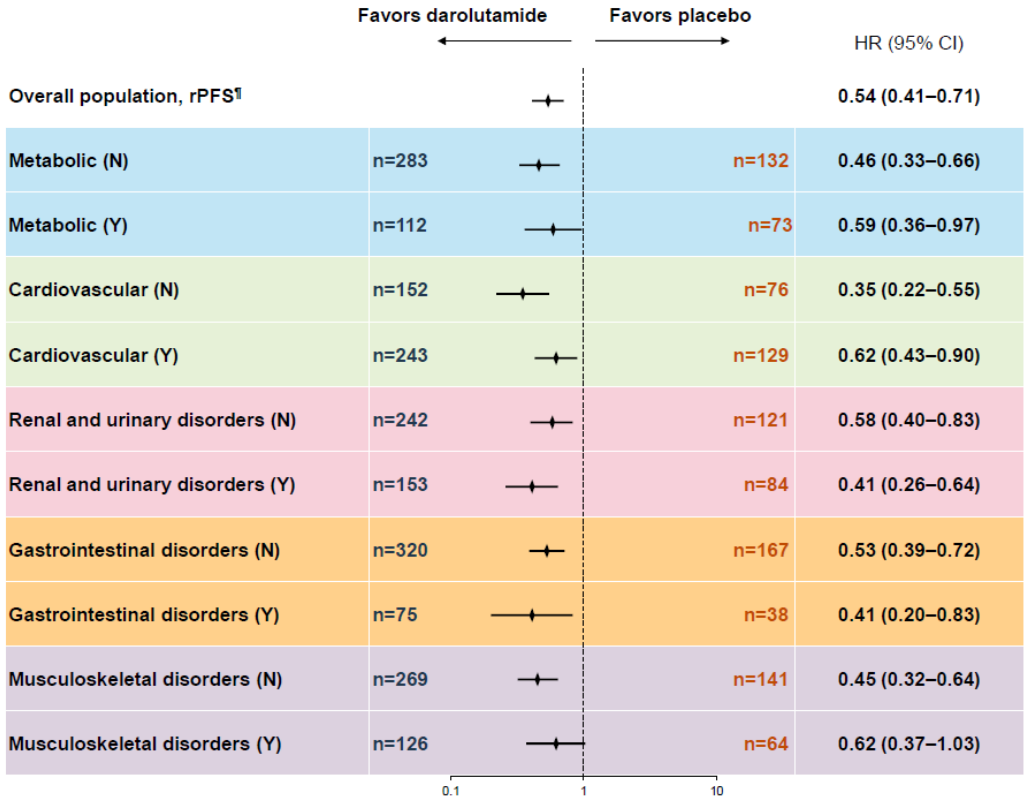


Figure adapted from Saad F, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 178.

ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; mHSPC, metastatic hormone-sensitive prostate cancer; N, no; rPFS, radiological progression-free survival; Y, yes.

Saad F, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 178.

Efficacy and safety of darolutamide and ADT in patient subgroups by baseline comorbidities and concomitant medications: ARANOTE post-hoc analyses

Summary

- Darolutamide plus ADT showed a rPFS benefit compared with placebo plus ADT across patient groups, whether they had few or many other health problems, or were taking few or many other medicines
- The benefit was seen across different types of comorbidities (metabolic, heart, kidney/urinary, gut, and muscle/bone issues) and was similar for patients with or without common conditions such as high blood pressure or diabetes
- The incidence and severity of TEAEs were generally similar between darolutamide and placebo across comorbidity subgroups, with slightly higher incidences in patients with more comorbidities

Author's conclusions: The rPFS benefit of darolutamide plus ADT was observed across all subgroups, regardless of the number of comorbidities (<5 or ≥5) and concomitant medications (<5 or ≥5) reported at baseline

These data support the use of darolutamide in mHSPC, even in patients with multiple comorbidities and greater use of concomitant medication

mHSPC, metastatic hormone-sensitive prostate cancer; rPFS, radiological progression-free survival; TEAE, treatment-emergent adverse event.

Saad F, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 178.

Real-world darolutamide safety and effectiveness in nmCRPC by LMA use: post-hoc analyses of DAROL interim analysis 4

Objective

To assess the safety and real-world efficacy of darolutamide plus ADT in patients with nmCRPC, with or without concomitant lipid-modifying agent (LMA)

Key result: survival outcomes

Darolutamide maintained effectiveness in patients receiving concomitant LMAs, with no difference in OS between ‘Any LMA’ and ‘No LMA’ subgroups

Metastasis-free survival favoured the ‘No LMA’ and ‘No statin’ subgroups, but not the ‘No rosuvastatin’ subgroup*

Effectiveness outcomes by concomitant medication

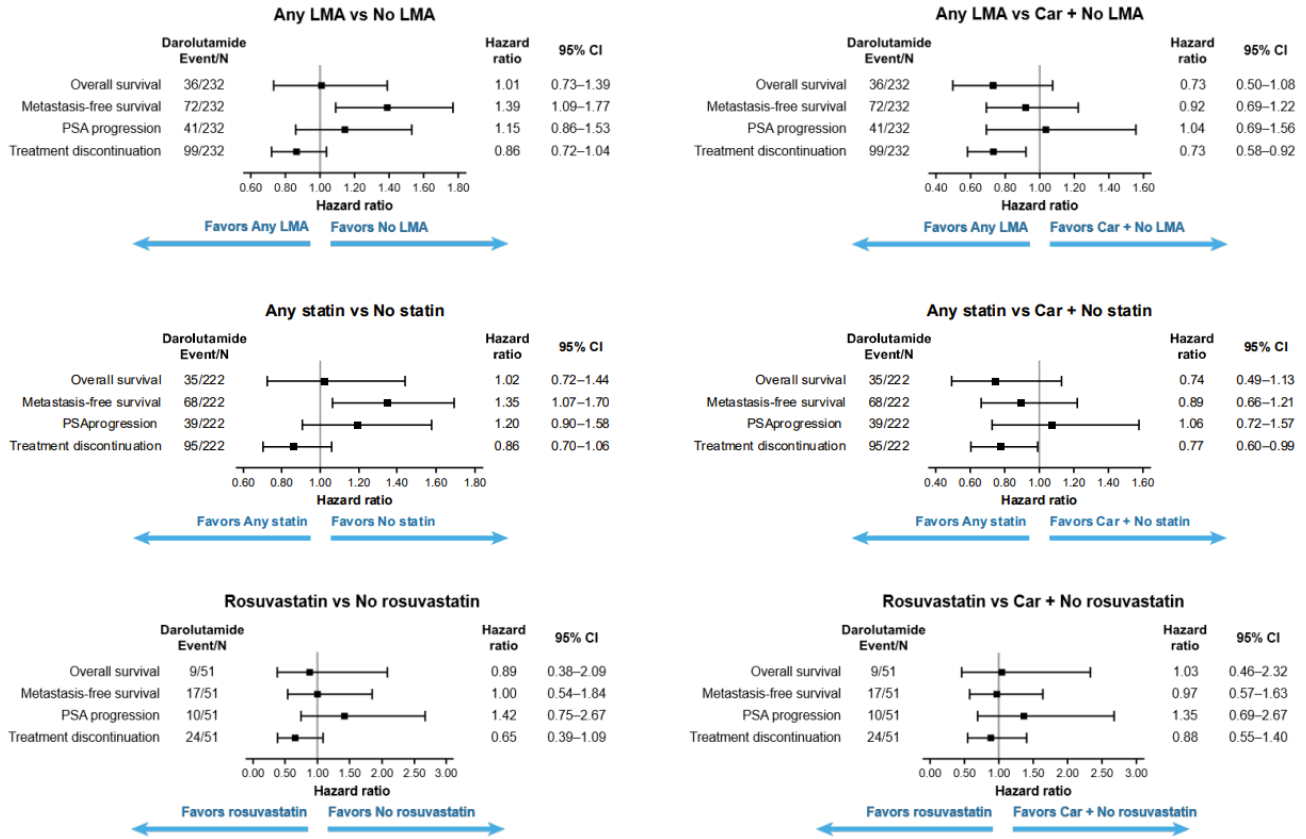


Figure adapted from Luz MA, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 99.

***See guidance on use of statins in patients receiving darolutamide before prescribing: NUBEQA® (darolutamide) Summary of Product Characteristics. Available at: https://https://www.medicines.org.uk/emc/product/11324/smpc#gref (accessed March 2026).**

Analysis used the ConcertAI Patient360 database. DAROL is an ongoing, international, multicenter, prospective, open-label, single-arm, non-interventional study in patients with nmCRPC treated with darolutamide according to local practice. Concomitant LMA use; defined as LMA starting before darolutamide and continuing during darolutamide therapy. Car, concomitant cardiac disease; CI, confidence interval; LMA, lipid-modifying agent; nmCRPC, nonmetastatic castration-resistant prostate cancer; OS, overall survival; PSA, prostate-specific antigen. Luz MA, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 99.

Real-world darolutamide safety and effectiveness in nmCRPC by LMA use: post-hoc analyses of DAROL interim analysis 4

Summary

- About a third of patients (32.3%) were on at least one LMA at the start of the study, most commonly atorvastatin, simvastatin or rosuvastatin[1]*
- Darolutamide was generally well tolerated in patients taking LMAs, with no new safety signals observed compared to those reported in the ARAMIS trial[2]
  - Compared with the 'No LMA' subgroup, the incidence of TEAEs was higher in the 'Any LMA' subgroup; no grade 5 events were treatment related
  - Fewer discontinuations due to TEAEs were seen in the 'Any LMA' subgroup compared with the 'No LMA' subgroup
- Darolutamide continued to work similarly in patients taking LMAs, including rosuvastatin, compared with patients not taking LMAs[1]

Author's conclusions: Data from the DAROL interim analysis 4 support darolutamide as a standard-of-care treatment option for patients with nmCRPC, including those receiving concomitant LMAs

***See guidance on use of statins in patients receiving darolutamide before prescribing: NUBEQA® (darolutamide) Summary of Product Characteristics. Available at: https://https://www.medicines.org.uk/emc/product/11324/smpc#gref (accessed March 2026).**

LMA, lipid-modifying agent; nmCRPC, nonmetastatic castration-resistant prostate cancer; TEAE, treatment-emergent adverse event.

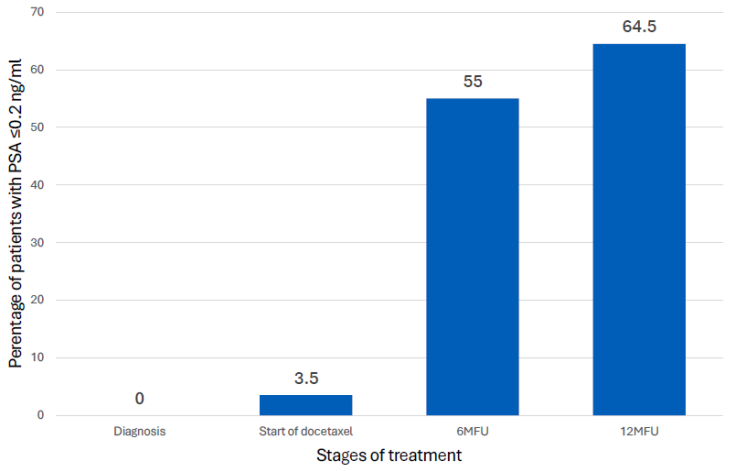
1. Luz MA, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 99; 2. Fizazi K, et al. N Engl J Med 2019;380:1235–1246.

Impact of age, cycles of chemotherapy and presence of visceral metastases on PSA response in patients on triplet therapy for mHSPC: UK real-world data from the RECOMMEND study

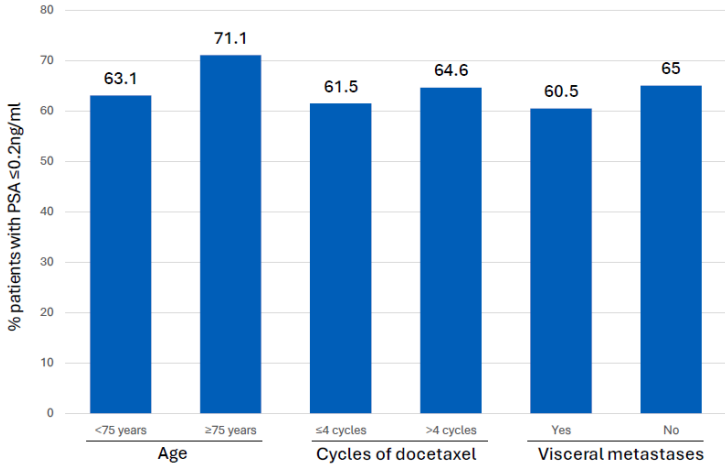
Objective

To report the outcomes of a prospective real-world study in patients with mHSPC receiving triplet therapy with darolutamide plus ADT plus docetaxel, in the UK

Effect of treatment on PSA response



Effect of age, cycles of docetaxel, and visceral metastases on PSA response at 12 months



Figures adapted from Bahl A, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 67.

Key result: PSA response

315 patients were enrolled across 21 centres in the UK

The percentage of patients with PSA levels ≤0.2 ng/ml increased from diagnosis during 12 months of triplet treatment

At 12 months follow up, there was no significant difference seen in the percentage of patients with PSA ≤0.2 ng/ml due to patient age (<75 vs ≥75 years), number of cycles of docetaxel received (≤4 vs >4 cycles) or visceral metastases (present vs absent)

Prospective real-world study of clinical outcomes in patients with mHSPC treated with triplet therapy (darolutamide + ADT + docetaxel) in the UK. Patients were enrolled over 20 months from November 2022. Patients were analysed using descriptive statistics for patient demographics; PSA changes with treatment were analysed.
ADT, androgen deprivation therapy; MFU, month follow up; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen.
Bahl A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco CA. Abstract 67.

Impact of age, cycles of chemotherapy and presence of visceral metastases on PSA response in patients on triplet therapy for mHSPC: UK real-world data from the RECOMMEND study

Summary

- In the RECOMMEND study, PSA response rates at 6 months and 12 months after starting darolutamide triplet therapy were similar, irrespective of age (<75 vs ≥75), number of cycles of docetaxel (≤4 vs >4) or the presence or absence of visceral metastases (lung/liver)[1]
- Efficacy seen in patients with mHSPC treated with ADT plus darolutamide plus docetaxel in the RECOMMEND study was similar to that reported in the ARASENS trial[1,2]

Author's conclusions: Data from this UK real-world study in patients with mHSPC adds to the existing clinical data, supporting patients and clinical teams in making informed treatment choices

ADT, androgen deprivation therapy; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen.

1. Bahl A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 67; 2. Smith MR et al. N Engl J Med. 2022;386:1132–1142.

Androgen-Receptor pAthwAy inhibitors Triplet therapy (ARAAT): real-world outcomes in mHSPC

Objective and method

To report the outcomes of a retrospective chart review cohort study in patients with mHSPC receiving triplet therapy with darolutamide plus ADT plus docetaxel **or** abiraterone plus ADT plus docetaxel*

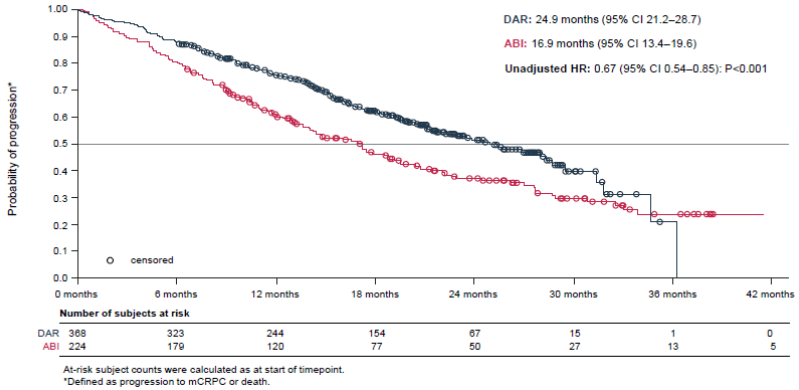
Analysis used the US-based Concert AI Patient360 database, a geographically diverse EMR source. IPTW and multivariate Cox proportional hazard models were applied to account for baseline confounding factors†

Key result: survival outcomes

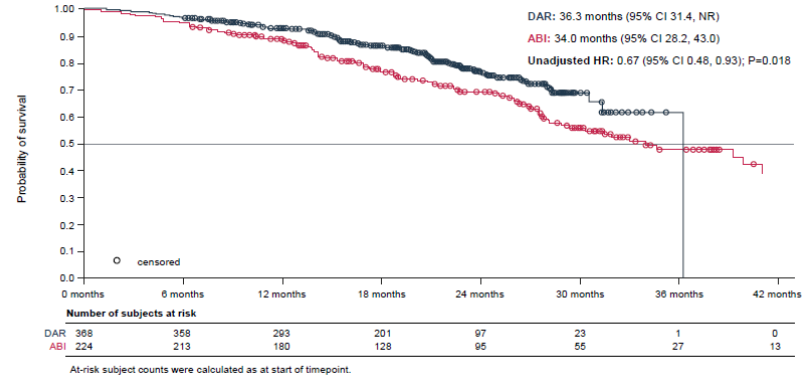
Of 592 eligible patients, 386 received darolutamide triplet therapy and 224 received abiraterone triplet therapy

Median OS and PFS were longer in patients receiving darolutamide-based treatment compared with those receiving abiraterone-based treatment

Median PFS



Median OS



Figures adapted from Morgans A, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 82.

***Abiraterone plus ADT plus docetaxel is not licenced in the UK.**

†Patients initiated triplet therapy with DAR or ABI between Jan 2020 – Jan 2025. Baseline confounding factors included age, race, insurance type, baseline PSA value, physician setting, region, ECOG PS, and time from metastasis to index date. Endpoints included time to PSA <0.2 ng/mL, TTD, TTNT, PFS (progression to mCRPC or death) and OS.

ABI, abiraterone + ADT + docetaxel; ADT, androgen deprivation therapy; CI, confidence interval; DAR, darolutamide + ADT + docetaxel; EMR, electronic medical record; HR, hazard ratio; IPTW, inverse probability of treatment weighting; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PFS, progression-free survival; PSA, prostate-specific antigen; TTD, time to treatment discontinuation; TTNT, time to next treatment.

Morgans A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 82.

Androgen-Receptor pAthwAy inhibitors Triplet therapy (ARAAT): real-world outcomes in mHSPC

Summary

- A total of 592 patients with mHSPC received ADT plus docetaxel combined with either darolutamide or abiraterone, in everyday practice
- Compared with patients who took abiraterone, patients who took darolutamide:
  - Had a higher likelihood of reaching PSA <0.2 ng/mL at 12 and 24 months of treatment, and reached PSA <0.2 ng/mL more quickly
  - Remained on treatment for longer
  - Had a longer time until they started a different treatment
  - Stayed alive for longer without their cancer progressing to more advanced disease
  - Survived for a longer time

Author's conclusions: Patients who received darolutamide triplet therapy had improved clinical outcomes compared with those who received abiraterone triplet therapy in this real-world study

ADT, androgen deprivation therapy; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen.

Morgans A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 82.

Determinants of treatment intensification in mHSPC: Institutional vs patient-level factors in a diverse UK multicentre cohort

Objective

To report the outcomes of a retrospective cohort study on the determinants of treatment intensification in patients with mHSPC in the UK, across institutional practice and patient-level factors

Key result: factors affecting treatment intensification

Among 173 eligible patients, treatment intensification was offered to 87% (151/173), with 79% (117/151) accepting

Older age was the only independent predictor of clinicians not offering treatment intensification, with minimal variation between clinicians

Acceptance of treatment intensification by patients was significantly lower in Black men, older patients and those with ECOG PS of 2

Retrospective cohort study; patients with mHSPC and ECOG PS 0–2 discussed at MDT meetings at Barts Health and Homerton NHS Trusts between March 2020 and December 2023. Mixed-effects multivariate logistic regression, with prescribing clinician as a random effect, was used to evaluate factors associated with treatment intensification offering and acceptance. Survival outcomes were assessed using Kaplan–Meier, Cox regression and restricted mean survival time analysis.
CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; MDT, multidisciplinary team; mHSPC, metastatic hormone-sensitive prostate cancer; OR, odds ratio.
Tyers B-L, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 40.

Factors affecting whether treatment was offered

Treatment Intensification Offered (n=174)	Univariate Logistic Regression			Multivariate Logistic Regression		
Characteristic	OR	95% CI	p-value	OR	95% CI	p-value
Age	0.87	0.81, 0.93	<0.001•	0.87	0.81, 0.94	<0.001•
Ethnicity (ref: White/Other)						
Black	0.73	0.28, 1.95	0.5	0.75	0.24, 2.32	0.62
Asian	0.46	0.13, 1.84	0.2	0.49	0.11, 2.26	0.36
Lives alone (ref: No)						
Yes	1.47	0.59, 4.01	0.4	–	–	–
CHAARTED criteria (ref: Low)						
High	1.68	0.62, 4.35	0.3	–	–	–
Visceral mets (ref: No)						
Yes	2.34	0.63, 15.2	0.2	–	–	–
CHAARTED (ref: High with visceral mets)						
High with bone mets only	0.67	0.15, 2.30	0.6	0.6	0.12, 2.97	0.54
Low	0.57	0.12, 2.15	0.4	0.38	0.07, 2.14	0.27
ECOG PS (ref: 0-1)						
2	0.34	0.13, 0.85	0.023*	0.38	0.13, 1.09	0.07
Charlson Comorbidity (ref: 0)						
≥1	0.79	0.33, 1.96	0.6	1.19	0.41, 3.50	0.75
IMD Decile	0.97	0.79, 1.23	0.8	1.04	0.81, 1.33	0.78

Factors affecting whether treatment was accepted

Treatment Intensification Acceptance (n=151)	Univariate Logistic Regression			Multivariate Logistic Regression		
Characteristic	OR	95% CI	p-value	OR	95% CI	p-value
Age	0.9	0.85, 0.94	<0.001*	0.9	0.85, 0.95	<0.001*
Ethnicity (ref: White/Other)						
Black	0.38	0.17, 0.84	0.018*	0.2	0.07, 0.56	<0.001*
Asian	0.82	0.22, 3.95	0.8	1.01	0.20, 5.14	0.99
Lives alone (ref: No)						
Yes	1.18	0.55, 2.62	0.7	–	–	–
CHAARTED criteria (ref: Low)						
High	0.73	0.30, 1.65	0.5	–	–	–
Visceral mets (ref: No)						
Yes	1.98	0.75, 6.22	0.2	–	–	–
CHAARTED (ref: High with visceral mets)						
High with bone mets only	0.53	0.16, 1.47	0.3	0.45	0.12, 1.63	0.22
Low	0.81	0.23, 2.65	0.7	0.6	0.14, 2.54	0.49
ECOG PS (ref: 0-1)						
2	0.33	0.14, 0.77	0.01*	0.27	0.10, 0.77	0.01*
Charlson Comorbidity (ref: 0)						
≥1	0.44	0.20, 0.94	0.035*	0.58	0.22, 1.52	0.27
IMD Decile	0.99	0.83, 1.21	>0.9	1.01	0.80, 1.29	0.9

Tables adapted from Tyers B-L, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 40.

Determinants of treatment intensification in mHSPC: Institutional vs patient-level factors in a diverse UK multicentre cohort

Summary

- Within an NHS setting, there was no evidence of institutional or physician bias in offering treatment intensification based on ethnicity and socioeconomic status, although younger patients were more likely to be offered treatment intensification
- Patient acceptance was influenced by ethnicity, ECOG PS and age

Author's conclusions: These findings highlight the importance of culturally sensitive, shared decision-making to improve equity in mHSPC treatment uptake and outcomes

ECOG PS, Eastern Cooperative Oncology Group performance status; mHSPC, metastatic hormone-sensitive prostate cancer.

Tyers B-L, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco, CA. Abstract 40.

NUBEQA® (darolutamide) 300 mg film-coated tablets
Prescribing Information – United Kingdom
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each film-coated tablet contains 300 mg of darolutamide. **Indication(s):** 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 androgen deprivation therapy or with mHSPC in combination with docetaxel. **Posology & method of administration:** Treatment should be initiated and supervised by a specialist physician experienced in treatment of prostate cancer. Medical castration with a luteinising hormone-releasing hormone (LHRH) analogue should be continued during treatment of patients not surgically castrated. For oral use. The tablets should be taken whole with food. ***Adults:*** 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. When used in combination with docetaxel in mHSPC patients, the first of 6 cycles of docetaxel should be administered within 6 weeks after the start of darolutamide treatment. Treatment with darolutamide should be continued until disease progression or unacceptable toxicity even if a cycle of docetaxel is delayed, interrupted, or discontinued. If a patient experiences a ≥ Grade 3 toxicity or an intolerable adverse reaction related to darolutamide, dosing should be withheld or reduced to 300 mg twice daily until symptoms improve. Treatment may then be resumed at a dose of 600 mg twice daily. ***Children & adolescents:*** There is no relevant use of darolutamide in the paediatric population. ***Elderly:*** No dose adjustment is necessary. ***Renal Impairment:*** No dose adjustment is necessary for patients with mild or moderate renal impairment. For patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) not receiving haemodialysis, the recommended starting dose is 300 mg twice daily. ***Hepatic Impairment:*** No dose adjustment is necessary for patients with mild hepatic impairment. The available data on darolutamide pharmacokinetics in moderate hepatic impairment is limited. Darolutamide has not been studied in patients with severe hepatic impairment. For patients with moderate and severe hepatic impairment (Child-Pugh Classes B and C), the recommended starting dose is 300 mg twice daily. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Warnings & precautions:** Monitor for signs and symptoms of ischaemic heart disease. Optimise management of cardiovascular risk factors. Discontinue darolutamide for Grade 3-4 ischaemic heart disease. Seizure occurred in patients receiving darolutamide. Advise patients of the risk of developing a seizure while receiving darolutamide. Consider discontinuation of darolutamide in patients who develop a seizure during treatment. Cases of idiosyncratic drug-induced liver injury (DILI) with increases in alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) to ≥5 and ≥20 x upper limit of normal (ULN) have been reported. Idiosyncratic DILI has been reported in clinical trials and the post-marketing setting. Liver function test abnormalities were reversible upon darolutamide discontinuation. In case of liver function test abnormalities suggestive of idiosyncratic drug-induced liver injury, permanently discontinue darolutamide. The available data in patients with severe renal impairment are limited. As exposure might be increased those patients should be closely monitored for adverse reactions. The available data in patients with moderate hepatic impairment are limited, and darolutamide has not been studied in patients with severe hepatic impairment. As exposure might be increased those patients should be closely monitored for adverse reactions. Patients with clinically significant cardiovascular disease in the past 6 months including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure were excluded from the clinical studies. Therefore, the safety of darolutamide in these patients has not been established. Use of strong CYP3A4 and P-gp inducers during treatment with darolutamide may decrease the plasma concentration of darolutamide and is not recommended, unless there is no therapeutic alternative. Selection of an alternate concomitant medicinal product with less potential to induce CYP3A4 or P-gp should be considered. Patients should be monitored for adverse reactions of BCRP, OATP1B1 and OATP1B3 substrates as co-administration with darolutamide may increase the plasma concentrations of these substrates. Co-administration with rosuvastatin should be avoided unless there is no therapeutic alternative. In patients with a history of risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating NUBEQA. NUBEQA 300mg film-coated tablets contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicinal product. **Interactions:** For the effect of other medicinal products on the action of darolutamide (e.g CYP3A4, P-gp inducers and CYP3A4, P-gp and BCRP inhibitors, UGT1A9 inhibitors and docetaxel) and the action of darolutamide on other medicinal products (BCRP, OATP1B1, OATP1B3 substrates, P-gp substrates, docetaxel, CYP3A4 substrates and other medicinal products that prolong the QT interval) refer to the relevant SmPCs. **Pregnancy & lactation:** Darolutamide is not indicated in women of childbearing potential, and it is not to be used in women who are, or may be, pregnant or breast-feeding. Unknown whether darolutamide or its metabolites are present in semen. If the patient is engaged in sexual activity with a woman of childbearing potential, a highly effective contraceptive method (<1% failure rate per year) should be used during and for 1 week after completion of treatment. Unknown whether darolutamide or its metabolites are excreted in human milk. No studies in animals have been conducted to evaluate the excretion of darolutamide or its metabolites into milk. A risk to the breast-fed child cannot be excluded. There are no human data on the effect of darolutamide on fertility. Based on animal studies, darolutamide may impair fertility in males of reproductive potential. **Effects on ability to drive and use machines:** Darolutamide has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** *Adverse reactions observed in patients with nmCRPC and mHSPC* *Very common:* fatigue/asthenic conditions, neutrophil count decreased, bilirubin increased, ALT increased, AST increased, anaemia. *Common:* ischaemic heart disease, heart failure, rash, pain in extremity, fractures. *Serious adverse reactions:* cardiac arrhythmias, urinary retention, urinary tract infection, pneumonia, fractures, seizure. *Adverse reactions observed in patients with mHSPC treated with darolutamide in combination with docetaxel*. *Very common:* hypertension, rash, blood bilirubin increased, ALT increased, AST increased. *Serious adverse reactions:* fractures, ischaemic heart disease, seizure, febrile neutropenia, neutrophil count decreased, pneumonia. Prescribers should consult the SmPC in relation to other side effects (see section 4.8 of SmPC). **Overdose:** In the event of intake of a higher than recommended dose, treatment with darolutamide can be continued with the next dose as scheduled. There is no specific antidote for darolutamide and symptoms of overdose are not established. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** Pack of 112 film-coated tablets, £4,040. **MA Number(s):** PLGB 00010/0677. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** June 2025

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store.
Adverse events should also be reported to Bayer plc.
Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com