THE RECOMMEND STUDY

Prospective **r**eal-world data **e**valuation of **c**linical **o**utco**m**es in **m**etastatic hormone se**n**sitive prostate cancer (mHSPC) patients treated as part of triplet therapy with **d**arolutamide: UK multicenter RECOMMEND study[1]

Triplet therapy: androgen-deprivation therapy (ADT) plus androgen receptor pathway inhibitor (ARPI) plus docetaxel

EXPERT INSIGHTS FROM THE QUICK DATA DIGEST PODCAST: ASCO-GU 2025. SCAN TO LISTEN.

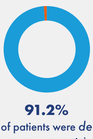
STUDY POPULATION

318
patients were enrolled from 21 UK centres*[1]

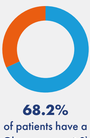
Median age of 67 (range 38–84) years[1]

*Bath, Blackburn, Bristol, Cambridge, Cheltenham, Clatterbridge, Colchester, Derby, Edinburgh, Glasgow, Hertfordshire (Mount Vernon), Kent, King's Lynn, Lancashire, Maidstone, Morecambe Bay, Nottingham, Royal Free, Stoke, Sussex, Swansea

BASELINE CHARACTERISTICS

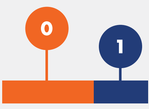


91.2%
of patients were *de novo* metastatic[1]

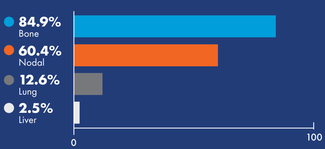


68.2%
of patients have a Gleason score ≥8[1]

Performance score[1]



The distribution of metastases (%) were[1]



RESULTS

At 6 months from darolutamide initiation, quality-of-life (QoL) data is currently available for 173 patients, of these

88.4%
reported either stable or improved QoL[1]

11.6%
had a decline in QoL at the end of chemotherapy[1]

The median PSA level was 134 (range 1 to 5628) ng/mL at diagnosis.[1] **At the end** of docetaxel chemotherapy, **median PSA was 0.35 ng/mL** (PSA_{50}, p=0.445; PSA_{90}, p=0.664)[1]

PSA response seen in the 226 patients who had completed 6 cycles of docetaxel chemotherapy at the data cut-off; PSA_{50} was seen in 87.6% (198/226) and PSA_{90} in 53.1% (120/226).[1]

CONCLUSIONS

The tolerability and efficacy of ADT + darolutamide + docetaxel in mHSPC in the RECOMMEND study are similar to the ARASENS trial.[1] QoL at 6 months is stable or improved in 88.4% of 173 patients, providing key real-world evidence for informed decision-making.[1]

ARASENS trial:

An international, phase 3 trial where patients with metastatic, hormone-sensitive prostate cancer were randomly assigned, in a 1:1 ratio, to receive darolutamide (at a dose of 600 mg [two 300-mg tablets] twice daily) or matching placebo, both in combination with androgen-deprivation therapy and docetaxel.[2]

The primary end point was overall survival.[2]

Adverse reactions reported in mHSPC patients treated with darolutamide in combination with docetaxel in the ARASENS study (with a ≥ 2% increase compared to placebo with docetaxel)[3]*

System organ class (MedDRA)	Very common
Vascular disorders	Hypertension[b]
Skin and subcutaneous tissue disorders	Rash[c,d]
Investigations*	Blood bilirubin increased ALT increased AST increased

* Adverse reactions incidences may not be attributable to darolutamide alone but may contain contributions from other medicinal products used in combination.
[b] Includes hypertension, blood pressure increased, hypertensive emergency.
[c] Includes rash, rash maculopapular, drug eruption, rash pruritic, rash erythematous, rash macular, rash papular, rash follicular, rash pustular, rash vesicular, erythema, dermatitis.
[d] The incidence was highest during the first 6 months of treatment.
[e] Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. The incidence is based on values reported as laboratory abnormalities.

References

1. Bahl M *et al. J Clin Oncol.* 2025;43(5_suppl):89
2. Smith MR *et al. N Engl J Med.* 2022;386(12):1132–1142
3. NUBEQA® (darolutamide) Summary of Product Characteristics. December 2024. Available at: https://www.medicines.org.uk/emc/product/11324/smpc (accessed March 2025)

RESOURCES

For further resources to support decision making regarding who is suitable for triplet therapy, please read a UK consensus publication assessing the clinical utility of triplet therapy using the QR code to the right.

Either click here or scan the QR code on the right for prescribing information and adverse event reporting information for NUBEQA (darolutamide). For direct access to this prescribing information, please ensure your device's browser settings have automatic PDF download enabled.

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