QUICK DATA DIGEST: SUMMARY – ASCO-GU 2026

Darolutamide studies

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STUDY ONE

ARANOTE *POST-HOC* ANALYSES: EFFICACY AND SAFETY OF DAROLUTAMIDE BY BASELINE COMORBIDITIES AND CONCOMITANT MEDICATIONS[1]

OBJECTIVE

To report outcomes in patients with mHSPC treated with darolutamide + ADT or placebo + ADT according to comorbidities and concomitant medications at baseline *

METHODOLOGY

This was a *post-hoc* analysis of the Phase III ARANOTE trial; patient subgroups were subdivided by <5 or ≥5 comorbidities or concomitant medications at baseline

RESULTS

Darolutamide + ADT showed a consistent benefit in rPFS vs placebo + ADT across comorbidity and concomitant medications subgroups

rPFS results were also consistent across different types of health problems, including metabolic, cardiovascular, renal or urinary, gastrointestinal and musculoskeletal disorders

The incidence and severity of TEAEs were generally similar between darolutamide + ADT and placebo + ADT across comorbidity subgroups, with slightly higher incidences in patients with more comorbidities

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

SPEAKERS' TAKEAWAYS

- Efficacy and tolerability of darolutamide + ADT vs placebo + ADT was consistent across subgroups, regardless of the number of comorbidities (<5 or ≥5) or concomitant medications (<5 or ≥5)
- Treatment efficacy with darolutamide was maintained even in patients with multiple comorbidities and polypharmacy, supporting its real-world use in an older population, which is commonly seen in clinical practice

STUDY TWO

ANDROGEN-RECEPTOR PATHWAY INHIBITORS TRIPLET THERAPY (ARAAT) STUDY[2]

This was a retrospective cohort analysis and not a head-to-head clinical trial.

OBJECTIVE

To report real-world effectiveness outcomes in patients with mHSPC receiving triplet therapy with darolutamide + ADT + docetaxel (DAR), or abiraterone + ADT + docetaxel (ABI)

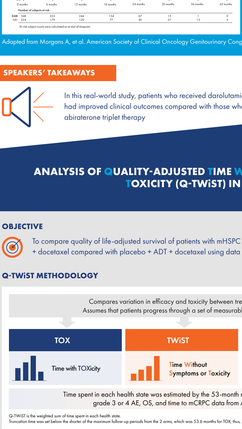
Abiraterone + ADT + docetaxel is not licensed in the UK.

METHODOLOGY

The ARAAT study was a retrospective chart review cohort study utilising US-based electronic medical records. IPTW and multivariate Cox proportional hazard models were applied to account for baseline confounding factors * *

RESULTS

Of 592 eligible patients with mHSPC, 368 (62%) received DAR and 224 (38%) received ABI



Median OS and PFS were longer in patients receiving darolutamide + ADT + docetaxel compared with those receiving abiraterone + ADT + docetaxel

Patients who received darolutamide-based treatment also had **improved outcomes** in terms of the probability of achieving a PSA level <0.2 ng/mL, median time to treatment discontinuation, and to the next treatment

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

SPEAKERS' TAKEAWAYS

In this real-world study, patients who received darolutamide triplet therapy had improved clinical outcomes compared with those who received abiraterone triplet therapy

STUDY THREE

ANALYSIS OF QUALITY-ADJUSTED TIME WITHOUT SYMPTOMS OR TOXICITY (Q-TWiST) IN PATIENTS WITH mHSPC[3]

OBJECTIVE

To compare quality of life-adjusted survival of patients with mHSPC receiving darolutamide + ADT + docetaxel compared with placebo + ADT + docetaxel using data from the ARASENS trial * * *

Q-TWiST METHODOLOGY

Compares variation in efficacy and toxicity between treatment arms
Assumes that patients progress through a set of measurable health states

TOX	TWiST	REL
Time with TOXicity	Time Without Symptoms or Toxicity	Time in RELapse or disease progression

Time spent in each health state was estimated by the 53-month restricted mean using grade 3 or 4 AE, OS, and time to mCRPC data from ARASENS

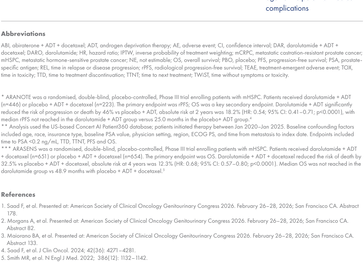
Q-TWiST is the weighted sum of time spent in each health state.
Truncation time was set below the shorter of the maximum follow-up periods from the 2 arms, which was 53.8 months for TOX; thus, 53 months was selected.

Adapted from Maiorano BA, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 133.

RESULTS

Patients receiving darolutamide triplet therapy (n=651) compared with placebo + ADT + docetaxel (n=654):

- had an **additional 6.3 months of survival** without symptoms or medical complications (p<0.001)
- had a **16% relative improvement** in quality time without symptoms or medical complications



Adapted from Maiorano BA, et al. American Society of Clinical Oncology Genitourinary Congress 2026. Abstract 133.

SPEAKERS' TAKEAWAYS

- The tolerability results from the Q-TWiST analysis were consistent to those demonstrated in the ARASENS trial
- These findings support the use of the ARASENS regimen as a treatment option in mHSPC, and may help physicians balance the survival benefits of treatment with darolutamide against the potential medical complications

Abbreviations

ABI, abiraterone + ADT + docetaxel; ADT, androgen deprivation therapy; AE, adverse event; CI, confidence interval; DAR, darolutamide + ADT + docetaxel; DARO, darolutamide; HR, hazard ratio; IPTW, inverse probability of treatment weighting; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; NR, not estimable; OS, overall survival; PBO, placebo; PFS, progression-free survival; PSA, prostate-specific antigen; REL, time in relapse or disease progression; rPFS, radiological progression-free survival; TEAE, treatment-emergent adverse event; TOX, time in toxicity; TTD, time to treatment discontinuation; TTNT, time to next treatment; TWiST, time without symptoms or toxicity.

* ARANOTE was a randomised, double-blind, placebo-controlled, Phase III trial enrolling patients with mHSPC. Patients received darolutamide + ADT (n=446) or placebo + ADT + docetaxel (n=223). The primary endpoint was rPFS; OS was a key secondary endpoint. Darolutamide + ADT significantly reduced the risk of progression or death by 46% vs placebo + ADT; absolute risk at 2 years was 18.2% (HR: 0.54; 95% CI: 0.41–0.71; p<0.0001), with median rPFS not reached in the darolutamide + ADT group versus 25.0 months in the placebo+ ADT group.[1]

* * Analysis used the US-based Concert AI Patient360 database; patients initiated therapy between Jan 2020–Jun 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 and OS.

* * * ARASENS was a randomised, double-blind, placebo-controlled, Phase III trial enrolling patients with mHSPC. Patients received darolutamide + ADT + docetaxel (n=651) or placebo + ADT + docetaxel (n=654). The primary endpoint was OS. Darolutamide + ADT + docetaxel reduced the risk of death by 32.5% vs placebo + ADT + docetaxel; absolute risk at 4 years was 12.3% (HR: 0.68; 95% CI: 0.57–0.80; p<0.0001). Median OS was not reached in the darolutamide group vs 48.9 months with placebo + ADT + docetaxel.[3]

References

1. Saad F, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco CA. Abstract 178.
2. Morgans A, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco CA. Abstract 82.
3. Maiorano BA, et al. Presented at: American Society of Clinical Oncology Genitourinary Congress 2026. February 26–28, 2026; San Francisco CA. Abstract 133.
4. Saad F, et al. J Clin Oncol. 2024; 42(16): 4271–4281.
5. *Smith MR, et al. N Engl J Med.* 2022; 386(12): 1132–1142.

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