



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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Darolutamide plus ADT and radiation therapy reduces risk of metastasis or death by 58% in prostate cancer patients at high risk of recurrence

- Interim analysis results from the Phase III trial DASL-HiCaP show a 58% reduction in the risk of metastasis or death in the combined primary endpoint of metastasis-free survival (MFS-CI) with darolutamide versus placebo, in addition to androgen deprivation therapy (ADT) and radiation therapy
 - Four-year metastasis-free survival rate in trial reached 95% with darolutamide compared to 88% with placebo, alongside secondary endpoint improvements and a safety profile consistent with previous studies
 - Results will be presented as a late-breaking abstract in a Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress 2026
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Berlin, October 24, 2026 – New late-breaking data to be presented today at the European Society for Medical Oncology (ESMO) Congress 2026 will show that adding Bayer's androgen receptor inhibitor (ARi), darolutamide, to standard-of-care androgen deprivation therapy (ADT) and locoregional radiation therapy (RT), significantly improves metastasis-free survival based on conventional imaging (MFS-CI) in prostate cancer patients with high risk of recurrence compared to placebo. Darolutamide is currently not approved for this treatment setting. These data will be presented at Presidential Symposium I at the ESMO Congress 2026 (LBA4, Saturday 24 October, 16:30 CET).

At a median follow-up of 3.8 years, the interim analysis demonstrated a 58% reduction in the risk of metastasis or death with darolutamide plus ADT and RT compared with placebo plus ADT and RT (hazard ratio [HR] 0.42; 95% CI: 0.27–0.66; $p=0.0001$). The 4-year metastasis-free survival rate was 95% for patients receiving darolutamide compared with 88% for those receiving placebo.

“Prostate cancer patients at a high risk of relapse face a considerable risk of recurrence and metastatic spread, making early, highly effective intervention vital,” said Dr. Tamim Niazi, Associate Professor of Oncology at McGill University, Radiation Oncologist at the Jewish General Hospital in Montreal, Canada. and Co-Lead Investigator of the study.

“The clear improvement in metastasis-free survival seen in interim results from the DASL-HiCaP trial highlights the potential of adding darolutamide to standard androgen deprivation therapy and radiation therapy to help prevent or delay disease progression in patients who are at high risk of progression despite receiving primary curative therapy.”

Secondary endpoints also showed consistent positive trends with darolutamide, with a 53% reduction in the risk of prostate-specific antigen progression free survival (PSA-PFS; HR 0.47; 95% CI: 0.33–0.67), and a 4-year PSA-PFS rate of 91% versus 83% with placebo. Prostate cancer-specific survival (PCSS) and overall survival (OS) hazard ratios were 0.58 (95% CI: 0.17–1.97; 99% vs 99% at 4 years) and 0.88 (95% CI: 0.49–1.59; 97% vs 95% at 4 years), respectively, with follow-up ongoing.

The safety profile of darolutamide was consistent with its known tolerability, with adverse events being similar to the placebo group. Proportions of patients experiencing Grade ≥ 2 adverse events of special interest for darolutamide versus placebo were: fatigue/asthenia (14% vs 10%), hypertension (7% vs 9%), fractures (2% vs 3%), and cardiac events (3% vs 3%). Any Grade ≥ 3 adverse event occurred in 43% of patients in the darolutamide group versus 36% in the placebo group.

“These new data highlight the potential of darolutamide to make a meaningful difference for patients earlier in the course of their prostate cancer,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization at Bayer’s Pharmaceuticals Division. “By advancing darolutamide into earlier disease settings, we aim to reach more patients across the prostate cancer care continuum. We are proud to support ANZUP, the Sydney Clinical Trials Centre, CCTG and international partners in research as we work together with the potential to improve outcomes for men living with prostate cancer.”

Follow-up of participants is continuing to provide further information on longer-term outcomes, including overall survival.

About the DASL-HiCaP trial (ANZUP1801)

The DASL-HiCaP trial is an investigator-initiated, randomized, placebo-controlled, Phase III trial (NCT04136353) evaluating darolutamide added to standard-of-care ADT and locoregional radiation therapy in prostate cancer patients at high risk of recurrence.

DASL-HiCaP was conducted in collaboration with the University of Sydney and ANZUP Clinical Trials Group and is the fourth Phase III trial for darolutamide. Following ARAMIS, ARASENS, and ARANOTE, which demonstrated darolutamide's efficacy and safety in advanced prostate cancer, DASL-HiCaP represents the first Phase III study of darolutamide in early prostate cancer.

A total of 1,106 participants across Australia, New Zealand, Canada, the United States, Ireland and the United Kingdom were randomized 1:1 to receive darolutamide (600 mg twice daily) or matching placebo for 96 weeks, combined with an LHRH analog for 96 weeks and RT to the prostate/prostate bed and pelvic lymph nodes.

The primary endpoint was metastasis-free survival based on conventional imaging (MFS-CI). Secondary endpoints included prostate-specific antigen progression free survival (PSA-PFS), prostate cancer-specific survival (PCSS), and overall survival (OS). The protocol specified an interim analysis after 87 MFS-CI events; follow-up is ongoing to evaluate long-term overall survival.

About the Sydney Clinical Trials Centre

The Sydney Clinical Trials Centre is a flagship research centre of the Faculty of Medicine and Health at the University of Sydney that designs and manages clinical trials. This includes responsibility for study coordination, monitoring, data acquisition and management and statistical analysis. The Sydney Clinical Trials Centre has health economics, biostatistics, systematic reviews and biomarker teams that work with trial data and inform healthcare providers about best practice. For further details, please visit its website at <https://www.ctc.usyd.edu.au>

About ANZUP Clinical Trials Group

ANZUP (<https://www.anzup.org.au>) is the leading cancer-cooperative trials group bringing together all of the professional disciplines and groups involved in researching and treating urogenital cancers to conduct high-quality cancer research. ANZUP's mission is to

improve the lives of people affected by bladder, kidney, testicular, penile, and prostate cancers, towards our vision of living life without fear of cancer. ANZUP identifies gaps in evidence and areas of clinical need, collaborates with the best clinicians and researchers in genitourinary cancer and communicates frequently and effectively with the broader community along the way. ANZUP receives valuable infrastructure support from the Australian Government through Cancer Australia and research funding from Prostate Cancer Foundation of Australia.

About Prostate Cancer

Prostate cancer is the second most common cancer and the fourth most common cause of cancer death in men worldwide. Over 1.5 million men are diagnosed with prostate cancer each year and almost 420,000 die from the disease worldwide. By 2040, prostate cancer diagnoses are projected to increase to 2.9 million.

Standard therapy for prostate cancer patients at high risk of recurrence combines radiation therapy with androgen deprivation therapy (ADT). However, despite this approach, a significant proportion of patients experience treatment failure, local recurrence, or distant metastases. Intensifying therapy early with an advanced androgen receptor inhibitor aims to improve long-term disease control and delay metastatic progression.

About darolutamide (Nubeqa™)

Darolutamide is an oral ARi with a distinct chemical structure that binds with high affinity to the androgen receptor and exhibits a strong antagonistic effect against the androgen receptor inhibiting the receptor function and growth of prostate cancer cells. Additionally, preclinical models and neuroimaging data in healthy humans support darolutamide's low potential for blood-brain barrier penetration and low potential for clinically relevant drug-drug interactions.

Darolutamide, under the brand name Nubeqa™ plus androgen deprivation therapy (ADT), is already approved in more than 85 markets around the world, including the US, EU and China. It is approved for the treatment of adult patients with mHSPC without docetaxel in 75 markets and with docetaxel in more than 85 countries, and for adult patients with nmCRPC at high risk of developing metastatic disease in more than 85 countries.

Darolutamide is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

Darolutamide demonstrated efficacy and tolerability in pivotal Phase 3 studies, supporting its indications in nmCRPC and mHSPC with and without chemotherapy, with a favorable safety profile that offers an advancement in treatment management for physicians and patients.

A robust clinical development program is underway investigating darolutamide across various stages of prostate cancer. Current ongoing trials include the Phase III ARASTEP trial evaluating the efficacy of darolutamide plus ADT compared to ADT alone in hormone-sensitive prostate cancer (HSPC), in patients with high-risk biochemical recurrence (BCR) who have no evidence of metastatic disease by conventional imaging and a positive PSMA PET/CT at baseline.

About Prostate Cancer at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop new medicines that help improve and extend the lives of people living with cancer. Prostate cancer is the second most commonly diagnosed cancer in men and a key area of focus for Bayer. The company's franchise includes two products on the market (Nubeqa™ and Xofigo™) and several compounds in development. Bayer is focused on addressing the unique needs of patients with prostate cancer, providing treatments that extend their lives throughout the different stages of the disease and allowing them to continue with their everyday activities, so that patients can live longer, better lives.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to support efforts to master major challenges presented by a growing and aging global population and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Lisa Hennig, phone +49 172 869 3420

Email: lisa.hennig@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/de/investoren/ir-team

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lh (2026-0177e)

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