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News Release

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Bayer's radium-223 dichloride plus enzalutamide demonstrates significant overall survival benefit in the PEACE-3 trial in patients with metastatic castration-resistant prostate cancer with bone metastases

- Final overall survival (OS) results from the PEACE-3 trial show enzalutamide in combination with radium-223 dichloride reduces the risk of death by 24% versus enzalutamide alone in men with metastatic castration-resistant prostate cancer (mCRPC) and bone metastases
 - PEACE-3 is the first randomized Phase III study to demonstrate a statistically significant improvement in both radiological progression-free survival and OS versus enzalutamide monotherapy in a bone-metastatic mCRPC
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Berlin, Germany and San Francisco, CA, USA, February 26, 2026 – The final results from the pivotal Phase III PEACE-3 trial demonstrated that first-line treatment with the androgen receptor inhibitor (ARI) enzalutamide in combination with radium-223 dichloride resulted in a significant overall survival (OS) benefit, reducing the risk of death by 24% versus enzalutamide alone in men with metastatic castration-resistant prostate cancer (mCRPC) and bone metastases. These data were presented in an oral session at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2026 (Oral abstract #15; February 26, 2026. 8:15 – 8:25 AM PST) and published simultaneously in [Annals of Oncology](#).

“Despite recent advances in prostate cancer care, many men with mCRPC and bone metastases continue to face a poor prognosis and a high risk of disease progression,” said Enrique Gallardo, MD, Parc Tauli Hospital Universitari, Sabadell, Spain, and first author and presenter of the study abstract on the EORTC 1333/PEACE-3 trial. “Results from PEACE-3 show that starting with enzalutamide in combination with radium-223, which targets both the cancer and the bone metastases, may help patients live longer

while supporting treatment strategies that prioritize bone health, an important consideration in helping men preserve function and retain their independence for longer.”

At the time of the final OS analysis, men receiving enzalutamide in combination with radium-223 demonstrated a statistically significant improvement in OS compared to those receiving enzalutamide alone, with a 24% reduction in risk of death (hazard ratio (HR)=0.76, 95% CI 0.60-0.96, p=0.0096). Median OS was 38.2 months with enzalutamide plus radium-223 versus 32.6 months with enzalutamide alone. The OS benefit was generally consistent across most predefined subgroups.

These final OS results build on the primary analysis, published in *Annals of Oncology*, which showed a significant improvement in radiological progression-free survival (rPFS) with the combination versus enzalutamide alone (19.4 vs. 16.4 months respectively; HR 0.69; 95% CI 0.54–0.87; p=0.0009).

“PEACE-3 is a strong example of how academic cooperative research can help advance progress for complex diseases such as metastatic prostate cancer,” said Denis Lacombe, Chief Executive Officer, European Organization for Research and Treatment of Cancer (EORTC). EORTC is a non-governmental, non-profit organization, which unites clinical cancer research experts throughout Europe to coordinate and conduct international translational and clinical research. “These Phase III data provide important insights for clinicians and underline the value of international collaboration in generating evidence that supports clinical decision-making.”

“These new PEACE-3 data reinforce Bayer’s leadership in prostate cancer care and our long-term commitment to addressing the unmet medical needs of patients,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “By investigating combination approaches, we are building a growing prostate cancer portfolio with the potential to bring new treatment options to patients across different stages of the disease.”

Radium-223 dichloride is approved under the brand name Xofigo® in more than 50 countries for the treatment of patients with mCRPC, who have symptomatic bone metastases and no known visceral metastatic disease.

About PEACE-3 (EORTC GUCG-1333)

The PEACE-3 trial is an international, randomized, open-label, Phase III trial designed to investigate the efficacy and safety of XOFIGO in combination with enzalutamide in patients with mCRPC and bone metastases. A total of 446 asymptomatic or mildly symptomatic patients (Brief Pain Inventory score <4) with mCRPC and ≥ 2 bone metastases were randomized 1:1 to receive enzalutamide 160 mg once daily alone or in combination with six intravenous injections of radium-223 dichloride (55 kBq/kg every four weeks).

The primary endpoint was radiological progression-free survival (rPFS) by investigator assessment. Key secondary endpoints included overall survival (OS), time to subsequent systemic treatment, pain progression, and symptomatic skeletal event.

This trial was a collaboration with several cancer cooperative groups: the European Organization for Research and Treatment of Cancer (EORTC), Clinical Trial Ireland (CTI), the Canadian Urological Oncology Group (CUOG), the Latin American Cooperative Oncology Group (LACOG), and French UNICANCER Urogenital Tumor Study Group (GETUG).

About Xofigo™ (radium-223 dichloride)

Xofigo™ is a therapeutic alpha particle-emitting pharmaceutical that emits radioactive alpha radiation and thus acts specifically against the cancer cells in the bones. In the EU, Xofigo monotherapy or in combination with luteinising hormone releasing hormone (LHRH) analogue is indicated for the treatment of adult patients with mCRPC, symptomatic bone metastases and no known visceral metastases, in progression after at least two prior lines of systemic therapy for mCRPC (other than LHRH analogues), or ineligible for any available systemic mCRPC treatment.

About Metastatic Castration-Resistant Prostate Cancer

Prostate cancer is the second most common cancer and the fifth most common cause of cancer death in men worldwide.¹ Around 1.5 million men are diagnosed with prostate cancer each year and about 397,000 die from the disease worldwide.¹ By 2040, prostate cancer diagnoses are projected to increase to 2.9 million.²

mCRPC is a stage where the cancer has stopped responding to hormone therapy and has spread to distant sites, particularly bone.³ Prognosis is poor, with a median survival of two to three years following diagnosis.⁴ Despite recent advances in prostate cancer care, patients continue to progress in mCRPC and mortality rates remain high, underscoring the necessity for new treatment approaches and combinations.^{3,4}

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 help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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¹ Bray F et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.2183>

² James ND et al. *Lancet* 2024; 403: 1683–722.

³ Saad F et al. *Eur Urol*. 2015 May 16;68(4):570–577

⁴ Raval AD et al. *Clin Genitourin Cancer*. 2025;23(5):102386