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News Release

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New data from global PAnTHa Phase I study presented at ASCO GU 2026

Bayer reports encouraging results for next generation investigational targeted radionuclide therapy ^{225}Ac -PSMA-Trillium in advanced metastatic prostate cancer

- ^{225}Ac -PSMA-Trillium (BAY 3563254) is an investigational targeted alpha therapy being developed for patients with advanced metastatic castration-resistant prostate cancer (mCRPC)
 - Promising data from PAnTHa, the global Phase I first-in-human, dose-escalation study were presented during the 2026 American Society of Clinical Oncology Genitourinary Cancers Symposium in San Francisco, CA, USA
 - Data support advancing ^{225}Ac -PSMA-Trillium to the next phase of development
 - Prostate cancer is the second most common diagnosed cancer in men¹, with less than three years median survival among metastatic patients, who have developed castration-resistance²
 - Targeted alpha therapy (TAT) is a strategic pillar of precision oncology at Bayer, with the potential to shift the treatment paradigm for patients
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Berlin, Germany and San Francisco, CA, USA, February 27, 2026 – Bayer today announced encouraging results from the ongoing global Phase I first-in-human, dose-escalation PAnTHa study (NCT06217822) evaluating the safety, tolerability and preliminary efficacy of ^{225}Ac -PSMA-Trillium (BAY 3563254), a next-generation targeted alpha therapy in patients with advanced metastatic castration-resistant prostate cancer (mCRPC). The dose for expansion was successfully identified, with $\geq 80\%$ of patients

¹ GLOBOCAN. World fact sheet. 2022. Available at: <https://gco.iarc.who.int/media/globocan/factsheets/populations/900-world-fact-sheet.pdf>. Accessed March 2024.

² Amit D Raval et al. Prediction model for real-world survival in men with castration-resistant prostate cancer and bone metastases in the United States: A real-world database study. JCO Oncol Pract 19, 507-507 (2023).

achieving a PSA50 response at the expansion dose. The new data were presented during the 2026 American Society of Clinical Oncology Genitourinary Cancers Symposium, taking place in San Francisco, CA, United States, from February 26-28, 2026. These clinical data represent the first disclosure for ^{225}Ac -PSMA-Trillium and were selected as part of the rapid oral session focused on advanced prostate cancer research. They support advancing ^{225}Ac -PSMA-Trillium to the next phase of clinical development. TAT is a strategic pillar of precision oncology at Bayer, with the potential to accelerate novel treatment options for patients with mCRPC.

“We are excited to see the encouraging results from the Phase I PAnTHa study demonstrating the potential of our novel targeted alpha therapy to advance outcomes for patients with advanced metastatic castration-resistant prostate cancer (mCRPC), a type of cancer with limited treatment options and poor prognosis,” said Dominik Ruettinger, M.D., Ph.D., Head of Research and Early Development for Oncology at Bayer’s Pharmaceuticals Division. “The development of ^{225}Ac -PSMA-Trillium confirms our ongoing focus on prostate cancer treatment and our continued drive to develop precise and personalized healthcare solutions, holding the promise to shift the treatment paradigm for patients.”

“Despite progress, patients with metastatic castration-resistant prostate cancer continue to face high mortality, highlighting the urgent need for new precision therapies,” said Fred Saad, MD, FRCS, Professor and Chairman of Surgery at the University of Montreal and Director of Genitourinary Oncology at the University of Montreal Hospital Center (CHUM), Canada. “ ^{225}Ac -PSMA-Trillium is a novel approach that could help address this need. The promising data support the further investigation of this molecule to provide a potentially meaningful clinical benefit for patients with mCRPC.”

^{225}Ac -PSMA-Trillium (BAY 3563254) is a next-generation investigational TAT labeled with actinium-225 and comprising a novel PSMA (prostate-specific membrane antigen)-targeting small molecule with a customized albumin-binding moiety. The compound is designed specifically to increase uptake within the tumor, with the goal to provide a differentiated safety and efficacy profile.

Prostate cancer is the second most commonly diagnosed cancer in men with less than three years median survival among metastatic patients, who have developed castration-

resistance. There is an increasing unmet need to improve the outcomes of men with mCRPC.

About the PAnTHa study (NCT06217822)

PSMA-targeted Actinium-225-Trillium FiH study in Advanced mCRPC (PAnTHa), is a Phase I, open-label, first-in-human, multicenter study to evaluate safety, tolerability, pharmacokinetics, and antitumor activity of ²²⁵Ac-PSMA-Trillium (BAY 3563254) in participants with advanced metastatic castration resistant prostate cancer (mCRPC) that have at least 1 PSMA-positive lesion on PSMA-PET. In the trial, patients received ²²⁵Ac-PSMA-Trillium intravenously every 6 weeks for up to 4 doses. At data cut-off, 50 patients were enrolled across four dose levels in the escalation cohort and 80% completed all four cycles of ²²⁵Ac-PSMA-Trillium (range: 75 to 150 kBq/kg; 12-13 patients/cohort).

Detailed Results from PAnTHa

No dose-limiting toxicities (DLTs) or treatment-related deaths have been observed to date. Of those patients eligible, 80% completed all four cycles of ²²⁵Ac-PSMA-Trillium. Most common treatment-emergent adverse events (TEAEs) were dry mouth, fatigue and nausea. Overall, 38% of patients had Gr ≥3 TEAEs, most commonly lymphopenia, 16% of patients had serious TEAEs and 4% of patients discontinued treatment due to TEAEs. The overall response rate per PCWG3 criteria across all doses in patients with measurable disease at baseline (n=24) was 46%, with disease control rate of 83%. Respective PSA50 and PSA90 response rates were 58% and 36% overall, and 83% and 58% at the Recommended Dose for Expansion (RDE). This was further supported by the robust decline in circulating tumor DNA (ctDNA) fraction at the RDE. Further, PSA50 responses were observed across all baseline mean Standardized Uptake Value (SUVmean) groups.

About ²²⁵Ac-PSMA-Trillium (BAY 3563254)

²²⁵Ac-PSMA-Trillium (BAY 3563254) is a next-generation trifunctional PSMA-targeting radiopharmaceutical that comprises a highly specific PSMA-targeting motif, an albumin-binding domain to optimize tumor uptake and retention, and a Macropa™ chelator complexed with the alpha-emitter actinium-225. The distinctive structural components are designed to improve therapeutic efficacy and reduce side effects. Both in vitro and in vivo characterization of ²²⁵Ac-PSMA-Trillium demonstrates high tumor uptake and retention. Potent antitumor efficacy has been observed in several preclinical models of prostate

cancer. PSMA-Trillium resulted from Bayer's acquisition of PSMA Therapeutics and Noria Therapeutics in 2021 and is now under clinical investigation.

About Targeted Alpha Therapy

Targeted alpha therapy (TAT) is an emerging class of radionuclide therapy that can be used against a variety of tumors. It delivers alpha particle radiation directly to the tumor inside the body, either via its bone-seeking property (radium-223) or by combining alpha radionuclides, such as actinium-225, with specific targeting moieties.

Actinium-225 is an alpha particle–emitting radionuclide with a 9.9-day half-life. Alpha particles deposit highly ionizing radiation over a short range. This localized delivery of the radioactive payload induces irreparable DNA double-strand breaks, often resulting in cell death. At the same time, because the energy travels a short range, damage to nearby normal tissues is much reduced.^{3,4,5}

About prostate cancer

Prostate cancer is the second most commonly diagnosed cancer in men. Despite significant advances in the last decade, the prognosis for men with mCRPC remains poor with a median survival of about 31 months.⁶ With increasing incidence, more than 300,000 prostate cancer cases were reported in the US in 2025; 5-year relative survival with distant disease is only 34%.⁷ Advances in imaging technologies (i.e. PSMA-PET) and their utilization across all stages of prostate cancer will likely result in an increased number of patients diagnosed with metastatic disease earlier. Consequently, more men will be diagnosed with *de novo* PSMA-positive metastatic disease.

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

³ Parker C, et al. JAMA Oncol. 2018;4(12):1765-1772. 2. 3.

⁴ Tafreshi NK, et al. Molecules. 2019;24(23):4314.

⁵ Hagemann UB, et al. Cancer Biother Radiopharm. 2020;35(7):497-510.

⁶ Amit D Raval et al. Prediction model for real-world survival in men with castration-resistant prostate cancer and bone metastases in the United States: A real-world database study. JCO Oncol Pract 19, 507-507 (2023).

⁷ Kratzer TB, Mazzitelli N, Star J, Dahut WL, Jemal A, Siegel RL. Prostate cancer statistics, 2025. CA Cancer J Clin. 2025; 75(6): 485-497. doi:10.3322/caac.70028

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

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.