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For Media and Investors only

Blue Earth Therapeutics announces first participant dosed in Phase 1 clinical trial investigating Actinium (^{225}Ac) rhPSMA-10.1 Injection in metastatic castration-resistant prostate cancer

The University College London (UCL) sponsored study evaluates safety, tolerability and radiation dosimetry of an investigational alpha-emitting PSMA-targeted radiopharmaceutical therapy, building on Blue Earth Therapeutics' radiohybrid platform.

OXFORD, UK, 9th July 2026

Blue Earth Therapeutics, a clinical-stage radiopharmaceutical company and University College London (UCL) today announced initiation of a Phase 1 clinical trial (NCT07414940) evaluating Actinium (^{225}Ac) rhPSMA-10.1 Injection, an investigational alpha-emitting PSMA-targeted radiopharmaceutical for the treatment of patients within clinical trials in metastatic castrate-resistant prostate cancer (mCRPC). The study is sponsored by UCL and is being conducted at UCL Hospital, London. Blue Earth Therapeutics is providing funding and supply of investigational drug product.

This Phase 1 study is designed to evaluate the safety and anti-tumour activity of Actinium (^{225}Ac) rhPSMA-10.1 Injection in participants with PSMA-positive mCRPC whose disease has progressed following prior therapy. Results from the study are expected to characterise the side effects of Actinium (^{225}Ac) rhPSMA-10.1 Injection and to inform dose selection for subsequent research.

Alpha-emitting radionuclides such as actinium-225 (^{225}Ac) deliver a high amount of energy over a short distance in tissue, causing irreparable DNA damage to targeted cancer cells whilst aiming to limit exposure to surrounding healthy tissue. When incorporated into a PSMA-targeting molecule such as rhPSMA-10.1, this approach is designed to deliver localised radiation directly to prostate cancer lesions, potentially offering a targeted treatment strategy for patients with advanced cancer.

Actinium (^{225}Ac) rhPSMA-10.1 Injection is the second clinical candidate in Blue Earth Therapeutics' oncology pipeline, building on the company's ongoing Lutetium (^{177}Lu) rhPSMA-10.1 Injection clinical programme, which is currently in a Phase 2 clinical trial. Together, these programmes reflect the company's work across both alpha- and beta-emitting radiopharmaceutical therapies using its radiohybrid PSMA platform.

UCL Cancer Institute director Professor Gert Attard said: "This study is an important step in advancing more precise treatment options for men with metastatic castrate-resistant prostate cancer. The combination of a highly targeted PSMA approach with the potent, short-range effects of an alpha-emitting radionuclide offers a promising strategy to deliver meaningful anti-tumour activity while limiting toxicity. Early-phase trials such as this are essential for determining safety, refining dose and guiding how these therapies can be integrated into personalised treatment pathways to improve outcomes for patients."

"Initiation of this collaborative Phase 1 study represents an important milestone for Blue Earth Therapeutics and our investigational radiopharmaceutical therapy pipeline," said Dr David Gauden, Chief Executive Officer of Blue Earth Therapeutics. "Building on our clinical experience in both alpha- and beta-emitting radiopharmaceutical therapies, we are combining the targeting precision of rhPSMA with the alpha-emitting properties of actinium-225 to explore a potential treatment approach for patients with advanced prostate cancer. We are very grateful to the team at UCL and to their patients for undertaking this study."

About metastatic prostate cancer

It has been forecast that in 2025 there would be 50,055 new cases of metastatic prostate cancer in the United States (de novo diagnoses plus recurrence from earlier stage diagnoses).[1] Five-year survival for newly diagnosed metastatic prostate cancer is low, 40.1%.[2] While death rates from prostate cancer have declined over the past three decades[2], there is still considerable room to improve patient outcomes.

About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)

rhPSMA compounds are referred to as radiohybrid ("rh"), as each molecule possesses four distinct domains. The first consists of a Prostate-Specific Membrane Antigen-targeted receptor ligand. It is attached to two labelling moieties which may be radiolabelled with diagnostic isotopes such as ^{18}F or ^{68}Ga for PET imaging, or with therapeutic isotopes such as ^{177}Lu or ^{225}Ac for radioligand therapy, all of which are joined together by a modifiable linker which can be

used to modulate important pharmacokinetic characteristics. Radiohybrid PSMA offers the potential for targeted treatment for men with prostate cancer and originated at the Technical University of Munich, Germany. Blue Earth Diagnostics acquired exclusive worldwide rights to rhPSMA diagnostic imaging technology from Scintomics GmbH in 2018, and therapeutic rights in 2020, and has sublicensed the therapeutic application to its sister company Blue Earth Therapeutics.

About Blue Earth Therapeutics

Blue Earth Therapeutics is a clinical stage company dedicated to advancing next-generation targeted radiotherapeutics to treat patients who have cancer and has been incubated within the Bracco family of companies. Other investors joined with Bracco in a Series A financing round in 2024. With proven management expertise across the spectrum of radiopharmaceutical and oncology drug development, as well as biotechnology start-up experience, the Company aims to innovate and improve upon current technologies and rapidly advance new targeted therapies for serious diseases. Blue Earth Therapeutics has an emerging pipeline initially focused on prostate cancer. For more information, please visit: https://www.blueearththerapeutics.com.

About Bracco

Bracco group, founded in 1927, is a global leader in diagnostic imaging, committed to advancing healthcare and improving people's lives by shaping the future of prevention and precision medicine.

The company operates in the healthcare sector across more than 100 countries with a workforce of over 4,000 employees and consolidated annual revenues of approximately €2 billion, 88% generated by international markets.

With a strong commitment to innovation - investing around 9% of its reference turnover in Research & Development - Bracco develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging, including contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well as microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside AI-based solutions. It is also a global market leader in advanced contrast management technologies for cardiovascular angiography and radiology imaging.

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Actinium (^{225}Ac) rhPSMA-10.1 Injection has not received a marketing authorisation in any country or region.

Lutetium (^{177}Lu) rhPSMA-10.1 Injection has not received a marketing authorisation in any country or region.

References:

1. Gallichio L *et al, JNCI J Natl Cancer Inst* (2022) 114(11): djac158
2. SEER 22 database, https://seer.cancer.gov/statfacts/html/prost.html, last accessed July 2026

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