PRESS RELEASE:

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First Patients in the UK Receive Doses of Blue Earth Therapeutics' Investigational Radiopharmaceutical Therapy Lutetium (^{177}Lu) rhPSMA-10.1 Injection for Metastatic Castrate Resistant Prostate Cancer

St Bartholomew's Hospital and The James Cook University Hospital mark key UK expansion of the company's Phase 2 mCRPC programme

- The patients received Lutetium (^{177}Lu) rhPSMA-10.1 Injections at both St Bartholomew's Hospital, London, and The James Cook University Hospital, Middlesbrough
- Lutetium (^{177}Lu) rhPSMA-10.1 Injection, engineered with the aim of improving delivery of radiation to the prostate cancer lesions whilst minimising exposure to normal organs
- Phase 1 part of the study reported positive results with encouraging radiation dosimetry[1]
- Phase 2 is designed to further assess safety, to assess efficacy and to evaluate novel dosing regimens

OXFORD, UK, 15th January 2026 – Blue Earth Therapeutics today announced that the first patients in the UK have been administered with the investigational radiopharmaceutical therapy Lutetium (^{177}Lu) rhPSMA-10.1 Injection in an ongoing Phase 2 clinical trial (NCT05413850) at St Bartholomew's Hospital and The James Cook University Hospital. This milestone marks continued expansion of the clinical development programme for the company's radiohybrid, lutetium-labelled, PSMA-targeted investigational radiopharmaceutical therapy in men with metastatic castration-resistant prostate cancer (mCRPC).

Dr Kenrick Ng, Medical Oncology Consultant, St Bartholomew's Hospital, London, said: *"Dosing one of the first patients in the UK in this Phase 2 study is an important milestone as we work to advance new therapeutic options for men with metastatic castration-resistant prostate cancer. Radiopharmaceuticals represent a promising area of investigation in this difficult-to-treat setting, and the team at our hospital is pleased to contribute to the generation of the clinical evidence needed to understand the potential of this investigational treatment."*

Dr Darren Leaning, Consultant Clinical Oncologist, The James Cook University Hospital, Middlesbrough, said: "*Bringing this study to the UK is an important step in expanding access to complex radiopharmaceutical trials. Delivering studies of this kind requires close collaboration across clinical, research, and nuclear medicine teams, we at the James Cook Cancer Institute pride ourselves on bringing studies like this to our Teesside patients and we are pleased to be working with colleagues at other NHS trusts and the radiopharmaceutical industry to support the generation of high-quality clinical data for patients with advanced prostate cancer.*"

The milestone of administering the first doses to patients in the UK highlights growing momentum for the Lutetium (^{177}Lu) rhPSMA-10.1 Injection clinical programme. Other sites in the UK are actively screening patients for this study. Activation of UK clinical sites broadens the study's international footprint and supports the generation of high-quality evidence across multiple healthcare settings. The expansion supports ongoing efforts to evaluate novel dosing strategies and contributes to the future global development of this PSMA-targeted radioligand therapy.

David Gauden, CEO of Blue Earth Therapeutics, said: "*Dosing the first patients in the UK marks a pivotal step in our mission to advance radiopharmaceutical treatments for prostate cancer. With our company being headquartered in the UK, this milestone reflects our commitment to the UK's life sciences vision to accelerate clinical research and translate innovation into meaningful patient benefit. We are proud to work in partnership with UK investigators, the NHS and patients to help strengthen the UK's position as a global leader in life sciences excellence.*"

The Phase 2 is evaluating multiple strategies to optimise dosing by delivering higher radiation doses during the early treatment cycles when tumour burden is typically greatest. This approach differs from earlier pivotal studies of radioligand therapies where fixed dosing was applied uniformly across all cycles[2]. The study design aligns with the US FDA's Project Optimus initiative, which encourages dose optimisation early in development to support a favourable benefit–risk profile.

Front loading of radioactivity in Phase 2 will be achieved either by (a) giving higher radioactivity injections in the first two cycles or (b) shortening the interval between the first three injections of radioactivity from six weeks to three weeks. The study also evaluates the potential clinical benefit of delivering higher cumulative administered radioactivity, up to 60 GBq. As part of the study design, the primary measure of efficacy will be the proportion of patients achieving a

≥50% reduction in prostate-specific antigen (PSA) levels alongside a detailed assessment of safety and capturing radiation dosimetry data for all patients.

About metastatic prostate cancer

In 2025 it is estimated that there will be 50,055 new cases of metastatic prostate cancer in the United States (de novo diagnoses plus recurrence from earlier stage diagnoses).[3] Five-year survival for newly diagnosed metastatic prostate cancer is low, 36.6%.[4] While death rates from prostate cancer have declined over the past three decades[4], 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 Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic

imaging agents and solutions. It offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. In 2019 Bracco Imaging enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. In 2021, Bracco Imaging established Blue Earth Therapeutics as a separate, cutting-edge biotechnology vehicle to develop radiopharmaceutical therapies. Visit: www.braccoimaging.com.

1. https://www.blueearththerapeutics.com/news
2. NCT04647526, NCT05204927, NCT04720157, NCT04689828
3. Gallichio L et al, JNCI J Natl Cancer Inst (2022) 114(11): djac158
4. SEER 22 database, https://seer.cancer.gov/statfacts/html/prost.html

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