PRESS RELEASE: intended for investment and finance professionals only
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Blue Earth Therapeutics Advances Clinical Development of Lutetium (^{177}Lu) rhPSMA-10.1 Injection with Promising Phase 1 Data

- *Phase 1 section of Phase 1/2 clinical trial has completed enrolment: transition to Phase 2 underway*
- *Clear regulatory feedback received on proposed Phase 2 study design opens new opportunities for innovative dosing regimens vs first generation radioligand therapies*

OXFORD, UK, October 8, 2024 – Blue Earth Therapeutics Ltd, an emerging leader in the development of therapeutic radiopharmaceuticals, today announced further positive developments for its novel investigational radioligand therapies. Enrolment of patients in the Phase 1 trial of Lutetium (^{177}Lu) rhPSMA-10.1 Injection was completed in July. Early data from the trial suggests an encouraging safety profile. Radiation dosimetry performed for up to three cycles showed delivery of high tumour absorbed radiation doses relative to the dose delivered to the key normal organs, such as kidney and salivary glands. While final analysis is ongoing, the ratio between radiation dose to tumours vs. dose to the kidneys and salivary glands was compelling vs. published data[1] for first generation radioligand therapies.

This data opens the way for the Phase 2 portion of the Phase 1/2 trial to start later this year. The company has shared the intended Phase 2 study design with regulators and, subject to trial safety committee agreement, will test innovative dosing regimens in the Phase 2 study. Based on the advantageous results for absolute tumour and normal organ uptake seen in Phase 1, the Phase 2 study will explore the following concepts:

1. Administration of a significantly higher overall injected radioactivity in comparison to recent Phase 3 clinical trials of other agents.
2. Front loading of administered radioactivity.
3. Extending duration of administration of radioactivity to provide longer time on treatment.

In combination with the positive radiation dosimetry results seen in Phase 1 for Lutetium (^{177}Lu) rhPSMA-10.1 Injection, these factors should further support the ultimate goal of delivering better outcomes for patients.

“We are excited by the new data which support our best-in-class thesis and to have a clear path to move from Phase 1 to Phase 2 in the development of our lead therapy,” said David Gauden, CEO. “We remain on track for the opening of Phase 2 in the next few months. We also expect to see the full Phase 1 results presented at a scientific meeting in 2025.”

“The available science increasingly highlights that fixed dosing at fixed intervals is unlikely to be optimal. Front loading radioactivity and extending the time on therapy may lengthen time to

disease progression. We will explore these concepts in Phase 2. Our intention is to optimize dosing now, with the aim of achieving the best possible outcomes for patients in a future pivotal trial," commented Dr Daniel Stevens, Head of Clinical Development and Medical at Blue Earth Therapeutics. "We think that adapting dosing based on data from the individual patient will be important for improved results."

The Phase 2 clinical trial of Lutetium (^{177}Lu) rhPSMA-10.1 Injection is planned to open at approximately 15 sites across the US and Europe and enroll approximately 70 patients.

[1] Ells, Zachary, et al. "Dosimetry of [^{177}Lu] Lu-PSMA-Targeted Radiopharmaceutical Therapies in Patients with Prostate Cancer: A Comprehensive Systematic Review and Meta analysis." Journal of Nuclear Medicine (2024).

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 radiolabeled 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. 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.

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