PRESS RELEASE:
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Blue Earth Therapeutics: SNMMI Presentation of Results from Lutetium (^{177}Lu) rhPSMA-10.1 Injection Phase 1 Clinical Trial

- *Results show delivery of high radiation doses to tumours compared with normal organs.*
- *Observed normal organ absorbed dosimetry results may allow administration of a high cumulative radioactivity.*
- *Ongoing Phase 2 study is testing the impact of administering a greater proportion of administered radioactivity during early treatment cycles.*

OXFORD, UK, 25 June 2025 – Blue Earth Therapeutics today announced radiation dosimetry results for its radiohybrid lutetium labelled, PSMA targeted, investigational radioligand therapy at the Society for Nuclear Medicine and Molecular Imaging (SNMMI) annual meeting. The Phase 1 clinical trial results were presented by Professor James Nagarajah of Radboud University Medical Centre, the Netherlands. Data were evaluated from 34 cycles of treatment across 13 metastatic castrate resistant prostate cancer patients in the radiation dosimetry portion of a Phase 1/2 clinical trial (NCT05413850) of Lutetium (^{177}Lu) rhPSMA-10.1 Injection.

The abstract can be found here:
https://www.xcdsystem.com/snmmi/program/B95p18u/index.cfm?pgid=2402&sid=46736&abid=146032

The data presented analysed tumour, kidney, salivary gland, and other healthy organ-absorbed radiation doses, and calculated tumour-to-kidney (T:K) and tumour-to salivary gland (T:S) ratios. These data used a tumour dosimetry methodology in which PET or SPECT scans identified lesions for evaluation that is in line with those reported in the literature for other radioligand therapies.

- Mean tumour-absorbed dose was 8.87 Gy/GBq
- Mean kidney-absorbed dose was 0.30 Gy/GBq
- Mean salivary gland-absorbed dose was 0.13 Gy/GBq
- The tumour:kidney ratio was 32.09
- The tumour:salivary gland ratio was 73.19

An additional “anatomy-based” dosimetry evaluation was also performed, which used tumour volumes defined only on CT scan by a blinded radiologist, thereby capturing all regions of the

tumour irrespective of uptake of the drug. In this analysis, the T:K and T:S ratios were 9 and 19, respectively.

David Gauden DPhil, CEO of Blue Earth Therapeutics, said, "Numerous studies across various cancer types have shown the therapeutic value of delivering high radiation doses to tumours. At the same time, due to the risk of normal organ toxicity, one cannot simply administer unlimited amounts of radioactivity to patients. The solution is to develop therapeutic agents that improve the tumour:normal organ ratios so that the proportion of injected radioactivity reaching the tumors is scaled up to maximise efficacy. The Phase 1 dosimetry data being presented here at SNMMI is an important validation of the concept that improved agents are possible. We look forward to the clinical efficacy results from the ongoing Phase 2 portion of the trial. In this phase, we may begin to see benefits driven by the unique properties of the rhPSMA molecule. Additionally, the novel dosing regimen, which is designed to deliver higher cumulative doses of radioactivity with front-loading in the early treatment cycles, could provide further therapeutic advantage."

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).[1] Five-year survival for newly diagnosed metastatic prostate cancer is low, 36.6%.[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 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.

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

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