



PRESS RELEASE

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Blue Earth Therapeutics Announces Publication of Results from Independent Clinical Experience with ¹⁷⁷Lu-rhPSMA-10.1 in Treatment of Metastatic Castrate Resistant Prostate Cancer

– First reported clinical results from independent clinical experience by University of Augsburg demonstrated encouraging preliminary data for ¹⁷⁷Lu-rhPSMA-10.1

– ¹⁷⁷Lutetium-labeled radiohybrid (rh) Prostate-Specific Membrane Antigen (¹⁷⁷Lu-rhPSMA-10.1) is now in clinical development as a highly optimized, next generation therapeutic radiopharmaceutical –

MONROE TOWNSHIP, N.J. and OXFORD, UK, February 20, 2024 – Blue Earth Therapeutics, a Bracco company and emerging leader in the development of innovative next generation therapeutic radiopharmaceuticals, is pleased to share the publication of promising early clinical data with ¹⁷⁷Lu-rhPSMA-10.1 from independent clinical experience by physicians at the University Hospital Augsburg, Germany.

NOTE: this early clinical experience with ¹⁷⁷Lu-rhPSMA-10.1, manufactured by the University Hospital Augsburg and used under German legislation, reflects use of an investigational agent for which safety and efficacy have not been established by the U.S. Food and Drug Administration.

The manuscript, “First Safety and Efficacy Data with the Radiohybrid ¹⁷⁷Lu-rhPSMA-10.1 for the Treatment of Metastatic Prostate Cancer,” has been published in the *Journal of Nuclear Medicine* (DOI <https://doi.org/10.2967/jnumed.123.266741>). In the 4 consecutive patients with metastatic prostate cancer who were evaluated, when looking at radiologic progression free survival (rPFS), 2 patients had not progressed at 24 and 18 months of follow-up. The other 2 patients had a rPFS of 12 and 15 months, respectively. Starting prostate-specific antigen (PSA) levels were reduced by 100%, 99%, 88% and 35% for the 4 individual patients. There were no serious treatment-related adverse events.

¹⁷⁷Lu-rhPSMA-10.1 is an investigational radiohybrid (rh) Prostate-Specific Membrane Antigen-targeted radiopharmaceutical for the treatment of prostate cancer, and the lead candidate in Blue Earth Therapeutics’ development of next generation therapeutic radiopharmaceuticals. The Company’s investigational Phase 1/2 clinical trial ([NCT05413850](https://clinicaltrials.gov/ct2/show/study/NCT05413850)) evaluating the safety, tolerability, dosimetry and anti-tumor activity of ¹⁷⁷Lu-rhPSMA-10.1 in eligible men with metastatic castrate-resistant prostate cancer (mCRPC) is underway in the United States.

“Although this experience with ¹⁷⁷Lu-rhPSMA-10.1 represents a small number of patients, we find the results encouraging, with durable radiologic responses for patients with metastatic castrate resistant prostate cancer, including a complete response to therapy sustained beyond two years,” said Prof. Dr. med. Constantin Lapa, Department of Nuclear Medicine, University Hospital, Augsburg, Germany. “This followed our previous dosimetry work with the same patients, which showed that ¹⁷⁷Lu-rhPSMA-10.1 achieved a high Therapeutic Index (TI), delivering a high dose to tumors relative to the absorbed dose to the kidneys, and we look forward to the results of Blue Earth Therapeutics’ ongoing Phase 1/2 trial.”

“We are pleased that these exciting data, from University Hospital Augsburg’s independent experience with ¹⁷⁷Lu-rhPSMA-10.1, have been made available to the physician community,” said David Gauden, D. Phil., Chief Executive Officer of Blue Earth Therapeutics. “These promising clinical data give us further optimism in advancing ¹⁷⁷Lu-rhPSMA forward in clinical development, with the hope to help treat patients with metastatic prostate cancer. ¹⁷⁷Lu-rhPSMA-10.1 is based on innovative radiohybrid PSMA theranostic technology, with a carefully optimized pharmacokinetic profile designed to increase retention in cancer deposits while encouraging clearance from normal tissues as rapidly as possible. We then match these properties with long-lived isotopes to maximize the therapeutic index and dose to tumor.”

About Blue Earth Therapeutics

Blue Earth Therapeutics, one of the Bracco family of companies, is a clinical stage company dedicated to advancing next generation targeted radiotherapeutics to treat patients who have cancer. 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, and with plans to expand into additional disease areas in oncology. Blue Earth Therapeutics is an indirect subsidiary of Bracco Imaging S.p.A., and based in Oxford, UK. 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: 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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