PRESS RELEASE

Blue Earth Therapeutics Announces U.S. FDA Clearance for Investigational New Drug (IND) Application for ^{177}Lu-rhPSMA-10.1 for Treatment of Prostate Cancer

– ^{177}Lutetium-labelled radiohybrid Prostate-Specific Membrane Antigen (^{177}Lu-rhPSMA-10.1) is a highly optimized, next generation therapeutic radiopharmaceutical –

– Newly launched Blue Earth Therapeutics rapidly advancing lead candidate into Phase 1/2 clinical development –

OXFORD, UK and BURLINGTON, Mass., April 12, 2022 – Blue Earth Therapeutics, a Bracco company and emerging leader in the development of innovative next generation therapeutic radiopharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug Application (IND) application for ^{177}Lu-rhPSMA-10.1. IND authorization to proceed enables Blue Earth Therapeutics to initiate a Phase 1/2 clinical study to evaluate the safety, tolerability, dosimetry and anti-tumor activity of ^{177}Lu-rhPSMA-10.1 in men with metastatic castrate-resistant prostate cancer (mCRPC). ^{177}Lu-rhPSMA-10.1 is the first clinical candidate in Blue Earth Therapeutics' oncology development program of next generation therapeutic radiopharmaceuticals. Blue Earth Therapeutics holds exclusive worldwide rights to therapeutic applications of radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) radiopharmaceutical technology to help advance the treatment of patients with prostate cancer.

"Clearance to proceed with this first clinical study for ^{177}Lu-rhPSMA-10.1 marks an exciting milestone for our new company, Blue Earth Therapeutics, and the patients with cancer that we hope to serve," said David E. Gauden, D.Phil., Chief Executive Officer of the Company. "We consider ^{177}Lu-rhPSMA-10.1 to be a next generation PSMA therapy with the potential to be best-in-class. ^{177}Lu-rhPSMA-10.1 is the result of a careful optimization process which aimed to maximize therapeutic index by delivering high radiation doses to prostate cancer lesions while sparing normal tissues wherever possible. Excitingly, this optimized technology can be developed with both beta- and alpha-emitting therapeutic radioisotopes. We look forward initially to applying our proven radiopharmaceutical development expertise in advancing ^{177}Lu-rhPSMA-10.1, and, over time, developing a pipeline of additional oncology therapeutics to help address significant unmet patient needs."

The trial is an open-label, multi-center, integrated Phase 1 and 2 study to evaluate the safety, tolerability, radiation dosimetry and anti-tumor activity of ^{177}Lu-rhPSMA-10.1 in men with metastatic castrate-resistant prostate cancer. Phase 1 will investigate the safety, tolerability and dosimetry of multiple cycles of ^{177}Lu-rhPSMA-10.1 in subjects with PSMA-positive mCRPC which has progressed following prior therapy. Results from Phase 1 will be used to determine the recommended treatment regimen to be tested in Phase 2. The Phase 1 study will be conducted at clinical sites in the United States, with further sites added for the Phase 2 component of the trial, in both the United States and Europe.

About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)

rhPSMA compounds are referred to as radiohybrid ("rh"), as each molecule possesses three distinct domains. The first consists of a Prostate-Specific Membrane Antigen-targeted receptor ligand which attaches to and is internalized by prostate cancer cells. It is attached to two labelling moieties which may be radiolabeled with either ^{18}F for PET imaging, or with isotopes such as ^{177}Lu or ^{225}Ac for therapeutic use – creating a true theranostic technology. They may play an important role in patient management in the future, and offer the potential for precision medicine for men with prostate cancer. Radiohybrid technology and rhPSMA originated from 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. Blue Earth Therapeutics and Blue Earth Diagnostics work closely on the development of ^{177}Lu-rhPSMA-10.1. Currently, rhPSMA compounds have not received regulatory approval.

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: 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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