Blue Earth Therapeutics Awarded UK MHRA Innovation Passport for Investigational ^{177}Lu-rhPSMA-10.1 for Treatment of Metastatic Castrate-resistant Prostate Cancer (mCRPC)

– ^{177}Lutetium-labeled radiohybrid Prostate-Specific Membrane Antigen (^{177}Lu-rhPSMA-10.1) is an optimized therapeutic radiopharmaceutical –

OXFORD, UK and MONROE TOWNSHIP, N.J., November 8, 2022 – Blue Earth Therapeutics, a Bracco company and emerging leader in the development of innovative next generation therapeutic radiopharmaceuticals, today announced that its investigational therapeutic radiopharmaceutical, ^{177}Lu-rhPSMA-10.1, has been awarded an Innovation Passport for the treatment of metastatic castrate-resistant prostate cancer. The Innovation Passport is a designation for innovative medicines and is the entry point to the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate time to market to facilitate patient access. The ILAP aims to achieve this goal by enabling enhanced coordination between sponsors and the UK Medicines and Healthcare products Regulatory Agency (MHRA), leading up to Marketing Authorization Application (MAA) submissions and by providing the opportunity for accelerated MAA reviews. The award was announced by the MHRA in partnership with other ILAP Steering Group members, The All Wales Therapeutics and Toxicology Centre, the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC).

"We are very pleased to be awarded the Innovation Passport, and believe that it recognizes the patient need for innovative radiopharmaceutical treatments having an optimized therapeutic index such as ^{177}Lu-rhPSMA-10.1 for prostate cancer," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Therapeutics. "We look forward to working closely with the MHRA and its partner agencies in developing a roadmap that can provide appropriate patients with accelerated access to next generation healthcare treatment."

About the Innovative Licensing and Access Pathway (ILAP)
ILAP was established in January 2021 as a new pathway that supports innovative approaches to the safe, timely and efficient development of medicines to improve patient access. It supports collaboration between the MHRA, its healthcare partners and the sponsoring pharmaceutical company. The ILAP is open to both commercial and non-commercial developers of medicines (UK based and/or global). It comprises of an Innovation Passport designation, a Target Development Profile (TDP) and provides companies with access to a toolkit to support all stages of the design, development and approvals process. The ILAP provides companies with opportunities for enhanced regulatory and other stakeholder input. Additional information is available on the UK government website.

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 (PSMA)-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.

Contact:

For Blue Earth Therapeutics (UK)
Clare Gidley
Associate Director Marketing and Communications
Tel: +44 (0) 7917 536939
clare.gidley@blueearthdx.com

For Blue Earth Therapeutics (U.S.)
Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917
priscilla.harlan@blueearthdx.com

Media

Sam Brown Inc.
Mike Beyer
(M) (312) 961-2502
mikebeyer@sambrown.com

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