



## PRESS RELEASE

### **Blue Earth Diagnostics Announces Data-sharing Agreement with Siemens Healthineers and the University Hospital of Technical University of Munich (TUM) for $^{18}\text{F}$ -rhPSMA-7.3, an Investigational PET Imaging Agent, to Support AI-based Algorithms Development**

**MONROE TOWNSHIP, NJ, and OXFORD, UK, October 18, 2022** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced the signing of a data-sharing agreement with Siemens Healthineers and the University Hospital of the Technical University of Munich (TUM) for anonymized  $^{18}\text{F}$ -rhPSMA-7.3 clinical data and images. Siemens Healthineers plans to evaluate the data to enhance its analytics and artificial intelligence (AI)-based algorithms for prostate cancer across its advanced PET/CT imaging software.  $^{18}\text{F}$ -rhPSMA-7.3 is an investigational radiohybrid (rh) Prostate-Specific Membrane Antigen-targeted PET imaging agent in development by Blue Earth Diagnostics for diagnostic imaging of newly diagnosed and biochemically recurrent prostate cancer.

“Blue Earth Diagnostics is committed to helping men with prostate cancer across the care continuum, and we recognize the importance of AI in advancing healthcare,” said David Gauden, D.Phil., Chief Executive Officer, Blue Earth Diagnostics. “AI-based algorithms have the potential to streamline the PET/CT analytical workflow for hospitals and imaging centers, by efficiently providing physicians with information critical to patient management and care, and freeing them to spend more time with patients. Blue Earth has a long-standing relationship with Siemens Healthineers, a leading medical technology company pioneering breakthroughs in healthcare. We are excited to collaborate on this project to facilitate provision of anonymized  $^{18}\text{F}$ -rhPSMA-7.3 data from TUM which will be used to enhance the analytical workflows for the Siemens Healthineers Biograph and *syngo.via* platforms. The project includes evaluation of diagnostic analytical techniques for  $^{18}\text{F}$ -rhPSMA-7.3 data as well as exploring their theranostic potential in radiopharmaceutical therapy. Looking forward, we also plan to make analytical data from Blue Earth Diagnostics’ Phase 3 clinical trials for  $^{18}\text{F}$ -rhPSMA-7.3 available, which includes robust histopathology data as the gold Standard of Truth.”

The agreement covers use of anonymized  $^{18}\text{F}$ -rhPSMA-7.3 PET/CT data from TUM by Siemens Healthineers to evaluate workflow improvements for image acquisition and interpretation; dose optimization; detection of small metastases and recurrent tumors; evaluation of patients in earlier stages of disease progression and stratification by low PSA levels; and, together with histopathology, assessment of the sensitivity of results. The data will also be used to define and optimize  $^{18}\text{F}$ -rhPSMA-7.3 workflow prior to PSMA-targeted radioligand therapy in prostate cancer, to assess its theranostic potential in therapeutic dose planning and the likelihood of treatment success.

“The TUM experience with rhPSMA has allowed us to investigate the potential performance of a new class of theranostic PSMA-targeting agents that enable efficient labelling with radioisotopes such as  $^{18}\text{F}$  for PET imaging or  $^{177}\text{Lu}$  for therapeutic use,” said Matthias Eiber, MD, PhD, Department of Nuclear Medicine, Klinikum rechts der Isar, TUM. “We are happy that  $^{18}\text{F}$ -rhPSMA-7.3 PET/CT imaging scans performed at TUM as part of routine patient care in prostate cancer can be part of this project to inform AI-based algorithms for improved PET/CT workflows. The use of AI has the potential to markedly

improve the quality of PET/CT as well as enhance the ability to interpret the scans and follow lesions over time. This will hopefully lead to expanded clinical use cases for this valuable technology, leading to better patient care.”

“We are pleased to collaborate with Blue Earth Diagnostics and TUM on this data-sharing agreement for  $^{18}\text{F}$ -rhPSMA-7.3,” said Bruce Spottiswoode, Director, Clinical Applications Research, Siemens Healthineers. “These data will help us optimize the acquisition and processing of  $^{18}\text{F}$ -based PSMA imaging and therapeutic radiopharmaceuticals across our family of PET/CT scanners and reading solutions.”

#### **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  $^{18}\text{F}$  for PET imaging, or with isotopes such as  $^{177}\text{Lu}$  or  $^{225}\text{Ac}$  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 Diagnostics has completed two Phase 3 clinical studies evaluating the safety and diagnostic performance of  $^{18}\text{F}$ -rhPSMA-7.3 PET imaging in prostate cancer: (“LIGHTHOUSE,” [NCT04186819](#)), in men with newly diagnosed prostate cancer, and “SPOTLIGHT,” [NCT04186845](#)), in men with recurrent disease. Currently, rhPSMA compounds have not received regulatory approval.

#### **About Blue Earth Diagnostics**

Blue Earth Diagnostics, an indirect subsidiary of Bracco Imaging S.p.A., is a growing international molecular imaging company focused on delivering innovative, well-differentiated diagnostic solutions that inform patient care. Formed in 2014, the Company’s success is driven by its management expertise and supported by a demonstrated track record of rapid development and commercialization of positron emission tomography (PET) radiopharmaceuticals. Blue Earth Diagnostics’ expanding oncology portfolio encompasses a variety of disease states, including prostate cancer and neuro-oncology. Blue Earth Diagnostics is committed to the timely development and commercialization of precision radiopharmaceuticals for potential use in imaging and therapy. For more information, please visit: [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.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](http://www.braccoimaging.com).

**Contact:**

**For Blue Earth Diagnostics (U.S.)**

Priscilla Harlan

Vice President, Corporate Communications

(M) (781) 799-7917

[priscilla.harlan@blueearthdx.com](mailto:priscilla.harlan@blueearthdx.com)

**For Blue Earth Diagnostics (UK)**

Clare Gidley

Associate Director Marketing and Communications

Tel: +44 (0)1865 784186

[clare.gidley@blueearthdx.com](mailto:clare.gidley@blueearthdx.com)

**Media**

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

[mikebeyer@sambrown.com](mailto:mikebeyer@sambrown.com)

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