



## PRESS RELEASE

### **Blue Earth Diagnostics Announces Key Results from Phase 3 SPOTLIGHT Study of <sup>18</sup>F-rhPSMA-7.3, an Investigational PET Imaging Agent, in Biochemical Recurrence of Prostate Cancer**

*– First results from SPOTLIGHT trial being presented at 2022 ASCO Genitourinary Cancers Symposium (ASCO GU) –*

*– Totality of results support Company proceeding with New Drug Application to U.S. Food and Drug Administration –*

**BURLINGTON, Mass. and OXFORD, UK, February 15, 2022** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced publication of key results from its Phase 3 SPOTLIGHT trial of <sup>18</sup>F-rhPSMA-7.3 in recurrent prostate cancer in an abstract being presented at the ASCO 2022 Genitourinary Cancers Symposium (ASCO GU). <sup>18</sup>F-rhPSMA-7.3 is an investigational Prostate-Specific Membrane Antigen-targeted radiohybrid (rh) PET imaging agent. The SPOTLIGHT study ([NCT04186845](https://clinicaltrials.gov/ct2/show/study/NCT04186845)) is a Phase 3, multi-center, single-arm imaging study, conducted in the United States and Europe to evaluate the safety and diagnostic performance of <sup>18</sup>F-rhPSMA-7.3 PET imaging in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy.

Based on the majority read results from the three blinded, independent PET readers, the overall detection rate (DR) of <sup>18</sup>F-rhPSMA-7.3 PET in the SPOTLIGHT study was 83% (322/389). When stratified by PSA level, the DRs in the 305 patients with prior prostatectomy were: PSA <0.5 ng/mL: 64% (77/120); PSA ≥0.5 and <1 ng/mL: 76% (51/67); PSA ≥1 and <2 ng/mL: 93% (41/44); PSA ≥ 2 and <5 ng/mL: 96% (43/45); PSA ≥ 5 and <10 ng/mL: 88% (14/16); and PSA ≥10 ng/mL: 100% (13/13).

The study was designed to confirm positive <sup>18</sup>F-rhPSMA-7.3 PET imaging findings using a composite Standard of Truth (SoT) consisting of either: histopathology (considered the gold standard); or conventional imaging (primarily with CT, bone scan or MRI, with fewer procedures using <sup>18</sup>F-fluciclovine PET). In 366 men with a composite SoT (histopathology and/or conventional imaging), the patient-level Correct Detection Rate (CDR) was 57% (95% CI, 52-62). The region-level Positive Predictive Value (PPV) was 60% (55-65). However, in the subset of patients using the preferred gold standard of histopathology as the SoT (n=69), the patient-level CDR and region-level PPVs were much higher, at 81% (70-90) and 72% (63-81), respectively, providing important evidence regarding <sup>18</sup>F-rhPSMA-7.3's performance. Additional endpoints, including patient-level PPV and the percentage of patients upstaged by <sup>18</sup>F-rhPSMA-7.3 PET, will be reported at future scientific meetings.

No serious adverse reactions were attributed to <sup>18</sup>F-rhPSMA-7.3 PET in the SPOTLIGHT study. Overall, 16 (4.1%) patients had at least one treatment-emergent adverse event that was considered possibly

related/related to  $^{18}\text{F}$ -rhPSMA-7.3. The most frequently reported events were: hypertension: 1.8% (n=7); diarrhea: 1.0% (n=4); injection site reaction: 0.5% (n=2), and headache: 0.5% (n=2).

The study will be discussed in an oral presentation at ASCO GU, “*Detection rate of  $^{18}\text{F}$ -rhPSMA-7.3 PET in patients with suspected prostate cancer recurrence: Results from a phase 3, prospective, multicenter study (SPOTLIGHT)*”, by Dr. David M. Schuster, MD, FACR, Winship Cancer Institute of Emory University, in person and online at the conference on Thursday, February 17, 2022, at 7:00 PM ET. The ASCO GU program guide is available [here](#).

“Up to 40% of patients who undergo radical prostatectomy, and up to 50% of patients who undergo radiation therapy will develop local or distant recurrences within 10 years, and the ability to determine the extent and location of recurrent prostate cancer to inform appropriate clinical management for these men is key for physicians and their patients,” said David M. Schuster, MD, FACR, Emory University School of Medicine, and Coordinating Investigator for the SPOTLIGHT study. “Conventional imaging techniques have many limitations in prostate cancer identification and localization, and greater imaging accuracy is needed throughout the care continuum, to optimize therapeutic decision-making. The Phase 3 SPOTLIGHT study investigated the diagnostic performance of  $^{18}\text{F}$ -rhPSMA-7.3 PET imaging as a potential decision-making aid in assessing suspected biochemical recurrence of the disease. Taken together, we believe these strong results support the clinical utility of  $^{18}\text{F}$ -rhPSMA-7.3 PET in men with recurrent prostate cancer across a wide PSA range.”

“We are pleased to share these key Phase 3 SPOTLIGHT study results with the clinical community at the prestigious ASCO GU 2022 conference,” said David Gauden, D.Phil., President R&D and Chief Scientific Officer of Blue Earth Diagnostics. “SPOTLIGHT is the first of Blue Earth’s diagnostic imaging rhPSMA trials to report results, based on novel radiohybrid PSMA technology which offers potential theranostic utility in both diagnostic PET imaging and therapy. We look forward to sharing these convincing results with the U.S. Food and Drug Administration (FDA) as part of a New Drug Application for  $^{18}\text{F}$ -rhPSMA-7.3 PET imaging.

Dr. Gauden continued, “Blue Earth is committed to helping men with prostate cancer across the care continuum, and we particularly wish to thank the patients and clinical teams who participated in the SPOTLIGHT study, despite the many challenges COVID-19 presented. In working to fulfill our commitment to patients, we are working on a uniquely comprehensive prostate cancer portfolio, which includes  $^{18}\text{F}$ -fluciclovine as well as investigational rhPSMA compounds for potential use in diagnostic PET imaging and targeted radiopharmaceutical therapy. Early studies of  $^{18}\text{F}$ -rhPSMA-7.3 demonstrated high binding affinity for PSMA, together with biodistribution data suggesting the potential for low bladder activity. Our focus on  $^{18}\text{F}$  as the isotope of choice for PET imaging with rhPSMA was made in consideration of its spatial resolution and resulting high quality of PET images, and its physical half-life which greatly facilitates ease of large-scale manufacturing and distribution for broad-based patient access.”

#### **About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)**

rhPSMA compounds consist of a radiohybrid (“rh”) Prostate-Specific Membrane Antigen-targeted receptor ligand which attaches to and is internalized by prostate cancer cells and they may be radiolabeled with  $^{18}\text{F}$  for PET imaging, or with isotopes such as  $^{177}\text{Lu}$  or  $^{225}\text{Ac}$  for therapeutic use – creating a true theranostic technology. The radiohybrid technology and rhPSMA originated from the Technical University of Munich, Germany. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA imaging technology from Scintomics GmbH in 2018, followed by acquisition of exclusive rights

to therapeutic applications in 2020. Blue Earth Diagnostics has two Phase 3 clinical studies evaluating the safety and diagnostic performance of  $^{18}\text{F}$ -rhPSMA-7.3 PET imaging in prostate cancer: (“SPOTLIGHT,” [NCT04186845](#)), in men with recurrent disease and (“LIGHTHOUSE,” [NCT04186819](#)), in men with newly diagnosed prostate cancer. 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 also 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. Visit: [www.braccoimaging.com](http://www.braccoimaging.com).

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