PRESS RELEASE

This press release is for U.S. audiences only

Blue Earth Diagnostics Announces Results on Clinical Factors Impacting Detection Rates from Phase 3 SPOTLIGHT Trial of Investigational PET Imaging Agent ^{18}F-rhPSMA-7.3 in Biochemical Recurrence of Prostate Cancer

– Oral presentation highlighted at American Society for Radiation Oncology (ASTRO) 2022 Annual Meeting –

MONROE TOWNSHIP, NJ, and OXFORD, UK, October 24, 2022 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced results from its Phase 3 SPOTLIGHT trial that evaluated the impact of various clinical factors, including baseline Prostate Specific Antigen (PSA) levels, PSA doubling time and Gleason score, on detection rates (DRs) for ^{18}F-rhPSMA-7.3 in recurrent prostate cancer. ^{18}F-rhPSMA-7.3 is an investigational high affinity radiohybrid (rh**)** Prostate-Specific Membrane Antigen-targeted PET imaging agent. The results were reported in an oral presentation at the American Society for Radiation Oncology (ASTRO) 2022 Annual Meeting in San Antonio, Texas.

"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, because 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," said Benjamin Lowentritt, MD, Chesapeake Urology Research Associates, Towson, Md., on behalf of the SPOTLIGHT Study Group. "A rising PSA after radical prostatectomy usually precedes a clinically detectable recurrence by years, but cannot differentiate between local, regional, or systemic disease. The utility of conventional imaging for the localization of recurrence is limited, particularly in patients with low PSA levels. Relapse after curative-intent primary treatment remains a considerable clinical burden, and precise imaging techniques are required to identify areas of involvement to facilitate the delivery of optimized patient management. These findings from the SPOTLIGHT study showed high DRs by majority read for ^{18}F-rhPSMA-7.3 PET over a wide range of baseline PSA levels."

"These results from the Phase 3 SPOTLIGHT trial in biochemically recurrent prostate cancer are included in our New Drug Application for ^{18}F-rhPSMA-7.3 PET imaging currently under review by the U.S. Food and Drug Administration, and we are pleased that they are being presented to the radiation oncology community at ASTRO 2022," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "In line with our mission to help patients with cancer across the care continuum, Blue Earth Diagnostics continues to develop our comprehensive prostate cancer portfolio, which includes ^{18}F-fluciclovine and investigational rhPSMA compounds for potential use in diagnostic PET imaging and targeted radiopharmaceutical therapy. ^{18}F-rhPSMA-7.3 represents a new class of PSMA-targeted PET

radiopharmaceuticals, with early studies ^{18}F-rhPSMA-7.3 showing a high binding affinity for PSMA, together with biodistribution data suggesting the potential for low bladder activity."

The findings presented at ASTRO included analyses of clinical factors impacting DRs for ^{18}F-rhPSMA-7.3 evaluated by three blinded central readers: DRs, including region-level analyses, stratified by baseline PSA levels, PSA doubling time, Gleason score and prior treatment (radical prostatectomy with or without radiotherapy, or radiotherapy only). For example, results showed that among the 389 patients in the Evaluable PET Scan Population, the patient-level DR of ^{18}F-rhPSMA-7.3 PET by majority read was 83% (322/389). When stratified by PSA level, the DRs were: PSA <0.5 ng/mL: 64% (77/121); PSA ≥0.5 and <1 ng/mL: 76% (51/67); PSA ≥1 and <2 ng/mL: 93% (42/45); PSA ≥2 and <5 ng/mL: 98% (86/88); PSA ≥5 and <10 ng/mL: 94% (34/36); and PSA ≥10 ng/mL: 100% (32/32). As noted previously, no serious adverse reactions were attributed to ^{18}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}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 SPOTLIGHT trial (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 ^{18}F-rhPSMA-7.3 PET imaging in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy. Key results for ^{18}F-rhPSMA-7.3 PET were previously presented at ASCO GU in February 2022,[1] with additional results announced at AUA in April 2022[2] and at SNMMI in June 2022.[3]

The findings were discussed in an oral presentation at ASTRO 2022 on October 24, 2022, "Impact of clinical factors on ^{18}F-rhPSMA-7.3 detection rates in men with recurrent prostate cancer: Findings from the phase 3 SPOTLIGHT study," by Benjamin Lowentritt, MD, Chesapeake Urology Research Associates, Towson, Md., on behalf of the SPOTLIGHT Study Group. Full session details and the abstract are available in the ASTRO online program HERE.

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}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 Diagnostics has completed two Phase 3 clinical studies evaluating the safety and diagnostic performance of ^{18}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 are investigational and 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.

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.

[1]DM Schuster, SPOTLIGHT Study Group. *J. Clin. Onc. 2022*; 40 (6_suppl):9-9.
[2]MT Fleming, SPOTLIGHT Study Group, *J. Urol*. 2022, 207 (5_suppl):31047.
[3]Kuo, P, SPOTLIGHT Study Group, *J. Nucl. Med.* 2022, 63 (2_suppl): 2539.

Contact:

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

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

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

# # #