PRESS RELEASE

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

– Oral presentation based on Late-breaking Abstract featured at American Urological Association's 2022 Annual Meeting (AUA2022) –

BURLINGTON, Mass. and OXFORD, UK, May 13, 2022 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced results of additional endpoints from its Phase 3 SPOTLIGHT trial of ^{18}F-rhPSMA-7.3 in recurrent prostate cancer. Results reporting the impact of ^{18}F-rhPSMA-7.3 PET on upstaging patients were reported in a Late-breaking Abstract oral presentation at the 2022 AUA Annual Meeting (AUA2022). ^{18}F-rhPSMA-7.3 is an investigational Prostate-Specific Membrane Antigen-targeted radiohybrid (rh) PET imaging agent.

"The ability to determine the extent and location of recurrent prostate cancer to inform appropriate clinical management is key for physicians and their patients, as 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 Mark T. Fleming, MD, Virginia Oncology Associates, US Oncology Research, Norfolk, Va., on behalf of the SPOTLIGHT Study Group. "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. These findings from the SPOTLIGHT study showed that 45 - 47% (113 - 117/250) of patients identified as negative on conventional baseline had at least one True Positive (confirmed by Standard of Truth) after lesion identified by ^{18}F-rhPSMA-7.3 PET. This frequently resulted in post-scan upstaging, particularly among patients with intact prostates. Actionable information such as this may help to define sites of disease recurrence and inform salvage therapy decisions."

"These results from the Phase 3 SPOTLIGHT trial are part of a New Drug Application with the U.S. Food and Drug Administration (FDA) for ^{18}F-rhPSMA-7.3 PET imaging, and we are pleased that they are being presented to the clinical community at the prestigious AUA2022 conference," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "In line with our mission to help patients with cancer, we continue to develop our uniquely 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 high affinity PSMA-targeted PET radiopharmaceuticals. Early studies of ^{18}F-rhPSMA-7.3 demonstrated high binding affinity for PSMA, together with biodistribution data suggesting the potential for low bladder activity."

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]

The findings presented at AUA2022 included Correct Detection Rate (CDR) assessment (the percentage of all patients scanned with at least one true positive PET finding as compared to the Standard of Truth of histopathology or confirmatory conventional imaging), and its impact on patient upstaging. They were based on individual read results from three blinded, independent PET readers. In total, the Efficacy Analysis Population (EAP) of 366 men had a composite Standard of Truth. Among EAP patients, 68% (250/366) had negative baseline conventional imaging. Among the 250 patients with negative baseline conventional imaging, ^{18}F-rhPSMA-7.3 showed a CDR of 45–47% (113 - 117/250) across the three readers.

Among patients who had undergone prostatectomy, 3.5-8.0% (7-16/201) of ^{18}F-rhPSMA-7.3 positive scans showed lesions in the prostate bed region, with 18-21% (36-43/201) in pelvic lymph nodes and 21-26% (43-52/201) in other sites that led to upstaging. Among patients who had received radiotherapy, these values were 39-41% (18-19/46), 6.5% (3/46) and 20-30% (9-14/46), respectively. Very few patients had an alternative primary therapy and no definitive conclusions could be drawn for them.

The Late-breaking Abstract was discussed in an oral Plenary Session presentation at AUA2022 on May 13, 2022, *"Impact of ^{18}F-rhPSMA-7.3 PET on upstaging of patients with prostate cancer recurrence: results from the prospective, Phase 3, multicenter SPOTLIGHT study,"* by Mark T. Fleming, MD, Virginia Oncology Associates, U.S. Oncology Research, Norfolk, Va., on behalf of the SPOTLIGHT Study Group. The *Journal of Urology* abstract is available 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.

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