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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

– Results at the American Urological Association's 2023 Annual Meeting (AUA2023) –

MONROE TOWNSHIP, NJ, and OXFORD, UK, April 29, 2023 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced additional results from its completed Phase 3 SPOTLIGHT trial of ^{18}F-rhPSMA-7.3 in recurrent prostate cancer, among a subgroup of patients who had undergone primary treatment with radiation therapy only. It evaluated the overall Detection Rates (DRs) of ^{18}F-rhPSMA-7.3 at patient level and stratified by anatomical region, Gleason score, baseline Prostate Specific Antigen (PSA) levels and PSA doubling time. ^{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 a moderated poster presentation at the American Urological Association's 2023 Annual Meeting (AUA2023), in Chicago, Ill.

"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 50% of patients who undergo radiation therapy will develop local or distant recurrences within 10 years," said Brian T. Helfand, MD, Chief of Division of Urology, NorthShore University HealthSystem, Evanston, Ill., on behalf of the SPOTLIGHT Study Group. "The utility of conventional imaging for the localization of recurrence is limited, and relapse after curative-intent radiation therapy remains a considerable clinical burden. Precise imaging techniques are required to identify areas of involvement in order to facilitate delivery of optimized management for patients. These findings from the Phase 3 SPOTLIGHT subgroup study showed high detection rates by majority read for ^{18}F-rhPSMA-7.3 across all regions. In particular, the finding that 43% (33/76) of men had distant extra-pelvic recurrences has important implications for clinical management, as procedures such as salvage prostatectomy would be futile in those cases."

"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 urology community at AUA 2023," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "^{18}F-rhPSMA-7.3 represents a new class of PSMA-targeted PET radiopharmaceuticals, with early studies showing a high binding affinity for PSMA, together with biodistribution data suggesting the potential for low bladder activity. The compound is part of Blue Earth Diagnostics' comprehensive prostate cancer

portfolio, which includes other compounds and this investigational rhPSMA compound for potential use in diagnostic PET imaging and targeted radiopharmaceutical therapy."

The findings presented at AUA included analyses of clinical factors impacting DRs for ^{18}F-rhPSMA-7.3 as evaluated by three blinded central readers: DRs, overall patient-level detection rate, and regional-level analyses, stratified by Gleason score, baseline PSA levels and PSA doubling time. For example, results showed that among the subgroup (n=76) of patients in the Evaluable PET Scan Population who had undergone primary treatment with radiation therapy for prostate cancer, the overall patient-level DR was 99% (75/76) and consistently high across the three independent readers (range 93-99%). Recurrence by region was 76% (58/76) for the prostate, 25% (19/76) for pelvic lymph nodes and 43% (33/76) for extra-pelvic recurrences. As noted previously, no serious adverse reactions were attributed to ^{18}F-rhPSMA-7.3 PET in the SPOTLIGHT study. Of the 391 patients who received ^{18}F-rhPSMA-7.3 in the SPOTLIGHT study, 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) was 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], at SNMMI in June 2022[3] and at ASTRO in October 2022[4].

The findings were discussed in a moderated poster presentation at AUA 2023 on April 29, 2023, "^{18}F-rhPSMA-7.3 Detection Rates in Patients with Recurrence of Prostate Cancer Following Primary Treatment with Radiation Therapy: Results SPOTLIGHT Study," by Brian T. Helfand, MD, NorthShore University HealthSystem, Evanston, Ill., on behalf of the SPOTLIGHT Study Group. Full session details and the abstract are available in the AUA 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]Schuster, DM, SPOTLIGHT Study Group, *J. Clin. Onc.* 2022; 40 (6_suppl):9-9.
[2]Fleming, MT, SPOTLIGHT Study Group, *J. Urol*. 2022; 207 (5_suppl):31047.
[3]Kuo, P, SPOTLIGHT Study Group, *J. Nucl. Med.* 2022; 63 (2_suppl):2539.
[4]Lowentritt, B, SPOTLIGHT Study Group, *Int. J. Radiat. Oncol. Biol. Phys.* 2022*;* 114(3):S130-S131.

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