**PRESS RELEASE**

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# Blue Earth Diagnostics Announces Reader Reproducibility Results 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 2022 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting –*

**BURLINGTON, Mass. and OXFORD, UK, June 15, 2022** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced inter- and intra-reader reproducibility results from its Phase 3 SPOTLIGHT trial of $^{18}$F-rhPSMA-7.3 in recurrent prostate cancer. Results for the inter-reader agreement showed that agreement was high across all readers. The inter-reader agreement for $^{18}$F-rhPSMA-7.3 PET/CT was more than 75% overall and greatest for the pelvic lymph node region, with more than 87% concordance. Intra-reader agreement was more than 85% overall. $^{18}$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 2022 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting.

"Biochemically recurrent prostate cancer can be locally recurrent disease, metastatic disease, or both. Therefore, optimal assessment of the extent and location of recurrent prostate cancer is critical for clinical decision-making by physicians and patients," said Phillip Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz. and Invicro, Needham, Mass., on behalf of the SPOTLIGHT study group. "Unfortunately, recurrence of prostate cancer is common. Conventional imaging, such as CT and bone scintigraphy, is often negative particularly when PSA is still low, so the demonstrated performance of PSMA-PET imaging fits an important unmet need. But no matter how good the radiotracer or scanner, reliable and consistent interpretation of PET imaging is foundational and has the potential to substantially impact patient care. These findings from the SPOTLIGHT study showed high inter-reader and intra-reader agreement for interpretation of $^{18}$F-rhPSMA-7.3 PET/CT scans in the setting of biochemical recurrence. Such high reproducibility, particularly for extra-prostatic regions, is clinically valuable, due to the potential of these findings to influence patient management."

"We are pleased to present these reader interpretation results from the Phase 3 SPOTLIGHT trial at SNMMI's 2022 Annual Meeting, as they will be a critical element of a New Drug Application with the U.S. Food and Drug Administration (FDA) for $^{18}$F-rhPSMA-7.3 PET imaging," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "In designing the image interpretation training to be used for the $^{18}$F-rhPSMA-7.3 Phase 3 program, we drew upon Blue Earth Diagnostics' expertise and experience in designing PET image interpretation programs and training for commercialized Axumin® (fluciclovine F 18). We selected $^{18}$F as the isotope of choice for PET imaging with rhPSMA 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. $^{18}$F-rhPSMA-7.3 represents a new class of high affinity PSMA-targeted PET radiopharmaceuticals. Early studies of $^{18}$F-rhPSMA-7.3 showed a binding affinity for PSMA, together with biodistribution data suggesting the potential for low bladder activity."

The findings presented at SNMMI discussed inter- and intra-reader agreement for the interpretation of $^{18}$F-rhPSMA-7.3 scans. Overall agreement between all three blinded readers who received identical training was assessed and repeated for the regions of the prostate/prostate bed, pelvic lymph nodes, and other (extra-pelvic) sites (lymph nodes outside pelvis, soft tissue/parenchyma, and bones). Results showed that agreement was high across all readers. The inter-reader agreement for $^{18}$F-rhPSMA-7.3 PET/CT was more than 75% overall and greatest for the pelvic lymph node region, with more than 87% concordance. Intra-reader agreement was more than 85% overall. Reproducibility was lower for the prostate/prostate bed than other regions; however, the high reproducibility for extra-prostatic regions is clinically valuable due to the potential of these findings to influence patient management.

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].

The findings were discussed in an oral presentation at SNMMI 2022 on June 14, 2022, "Inter- and intra-reader reproducibility of $^{18}$F-rhPSMA-7.3 PET image interpretation in patients with suspected prostate cancer recurrence: Results from a phase 3, prospective, multicenter study (SPOTLIGHT)," by Phillip Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz. and Invicro, Boston, Mass., on behalf of the SPOTLIGHT study group. Full session details and the abstract are available in the SNMMI 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.

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