



PRESS RELEASE

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Blue Earth Diagnostics Announces Additional Results from Phase 3 LIGHTHOUSE Trial of Investigational PET Imaging Agent ¹⁸F-rhPSMA-7.3 in Newly Diagnosed Prostate Cancer

– Results presented at 2023 ASCO Genitourinary Cancers Symposium (ASCO GU) –

MONROE TOWNSHIP, NJ, and OXFORD, UK, February 16, 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 Phase 3 LIGHTHOUSE trial that evaluated the diagnostic performance and safety of ¹⁸F-rhPSMA-7.3 in newly diagnosed prostate cancer. ¹⁸F-rhPSMA-7.3 is an investigational high affinity radiohybrid (rh) Prostate-Specific Membrane Antigen-targeted PET imaging agent. The results were reported in a presentation at the 2023 ASCO Genitourinary Cancers Symposium (ASCO GU), held February 16 -18, in San Francisco, Calif.

“Up to 25% of patients with primary prostate cancer may have detectable regional pelvic lymph node metastases, which are correlated with a risk for recurrence and associated overall survival,” said Brian F. Chapin, MD, Associate Professor, Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center, and Coordinating Investigator of the LIGHTHOUSE study. “Effective staging in primary disease – determining its presence and whether it may have metastasized – is critical in establishing optimal clinical management strategies. Pelvic lymph node dissection (PLND), or pelvic lymphadenectomy, is considered the gold standard in assessing pelvic node lesions, but its use is limited to the planned surgical area. Conventional imaging techniques such as CT and MRI are limited in the information they may provide. An ideal staging technique for detecting metastatic prostate cancer should include both pelvic nodes as well as more distant soft tissue and skeletal findings. The LIGHTHOUSE study looked at unfavorable intermediate, high and very high risk patients who were scheduled for radical prostatectomy plus PLND prior to ¹⁸F-rhPSMA-7.3 PET. Results were encouraging and showed that between 9% - 13% (28 and 42/314, respectively), across the readers, of patients for whom conventional imaging was negative, actually had distant (M1) metastatic lesions that were visible on ¹⁸F-rhPSMA-7.3 PET. Thus, ¹⁸F-rhPSMA-7.3 PET provided clinically valuable information prior to surgery that would likely result in management changes for these patients.”

“We are pleased to share these results from the Phase 3 LIGHTHOUSE study with the clinical community at ASCO GU 2023, as they are included in our New Drug Application for ¹⁸F-rhPSMA-7.3 PET imaging, which is currently under review by the U.S. Food and Drug Administration,” said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. “¹⁸F-rhPSMA-7.3 represents a new class of PSMA-targeted PET radiopharmaceuticals based on novel radiohybrid technology PSMA technology, which offers potential theranostic utility in both diagnostic PET imaging and therapy. Early studies with ¹⁸F-rhPSMA-7.3 potentially show a high binding affinity for PSMA, and biodistribution data suggest the potential for low bladder activity. We believe that these attributes will make it a valuable diagnostic tool that is radiolabeled with ¹⁸F for high image quality and readily available patient access.”

The findings presented at ASCO GU 2023 included assessment of the Verified Detection Rate (VDR) of distant metastatic (M1) lesions by ¹⁸F-rhPSMA-7.3 PET imaging. VDR was the proportion of patients with M1 lesions identified by blinded image evaluation and also subsequently confirmed as True Positive (TP) by biopsy (used in ~15% of M1 positive cases) or follow-up conventional imaging (used in ~85% of M1 positive cases). Findings were based on individual read results from 3 blinded, independent PET readers. Men with treatment-naïve, unfavorable intermediate to very high-risk prostate cancer who were scheduled to undergo radical prostatectomy and PLND underwent PET imaging after administration of ¹⁸F-rhPSMA-7.3. Onsite readers interpreted the images before submission for blinded interpretation and evaluation by the central readers.

Of the 335 men analyzed (median [range] PSA, 8.89 [1.15-120] ng/mL), 16-28% (53-93) had M1 lesions across the 3 readers. In total, 10-15% (35-49) had verified M1 lesions. By region, verified M1 lesions were most common in bone, ranging from 6.0-11% across readers. Similar data were shown among a subgroup who had negative baseline conventional imaging. In these 314 patients, the VDR ranged from 9-13% across readers, with bone showing the highest regional VDR, ranging from 5-9%.

The LIGHTHOUSE Phase 3 clinical trial ([NC04186819](#)) was a prospective, Phase 3, multi-center, single-arm, imaging study conducted in the United States and Europe to evaluate the safety and diagnostic performance of ¹⁸F-rhPSMA-7.3 PET in men with newly diagnosed prostate cancer. Results for the co-primary endpoints of efficacy and safety for the LIGHTHOUSE trial were previously presented at the 23rd Annual Scientific Meeting in Urologic Oncology (SUO) in December 2022.¹

The most recent findings, which reflect an analysis of additional LIGHTHOUSE study endpoints, “Detection of true positive M1 lesions by ¹⁸F-rhPSMA-7.3 PET in newly diagnosed prostate cancer: Results from the phase 3 prospective LIGHTHOUSE study,” were presented at ASCO GU 2023 on February 16, 2023, by Brian F. Chapin, MD, Associate Professor, Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center, on behalf of Bridget F. Koontz, MD, Duke University Medical Center (at the time of the study), for the LIGHTHOUSE Study Group. Full session details and the abstract are available in the ASCO GU 2023 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 ¹⁸F for PET imaging, or with isotopes such as ¹⁷⁷Lu or ²²⁵Ac 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 ¹⁸F-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.

¹Chapin BF, LIGHTHOUSE Study Group. 134: Diagnostic performance and safety of ¹⁸F-rhPSMA-7.3 PET in patients with newly diagnosed prostate cancer: Results from a phase 3, prospective, multicenter study (LIGHTHOUSE). SUO Annual Meeting. Orlando, FL: <https://suo-abstracts.secure-platform.com/a/gallery/rounds/15/details/2390>, 2022.

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