PRESS RELEASE

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Blue Earth Diagnostics Announces Reader Reproducibility Results from Phase 3 LIGHTHOUSE Trial of POSLUMA® (Flotufolastat F 18) Injection in Newly Diagnosed Prostate Cancer

– Oral presentation highlighted at 2023 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting –

MONROE TOWNSHIP, NJ and OXFORD, UK, June 27, 2023 – 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 LIGHTHOUSE trial of POSLUMA® (flotufolastat F 18) injection (formerly referred to as ^{18}F-rhPSMA-7.3) in newly diagnosed prostate cancer. Results showed high inter-reader agreement across all 3 trained, blinded readers. The inter-reader agreement for POSLUMA PET/CT in 352 evaluable scans was ≥95% across pair-wise inter-reader comparisons. Overall intra-reader agreement was ≥96% for each reader. Recently approved by the U.S. FDA, POSLUMA is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. The results were reported in an oral presentation at the 2023 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting.

“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 Phillip H. Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering. “Effective staging in primary disease − determining its presence and whether it may have metastasized − is critical to establishing optimal clinical management strategies for patients. Conventional imaging techniques are limited in the information they may provide, so the demonstrated performance of PSMA-PET imaging fits an important unmet need. As well, reliable and consistent interpretation of PET imaging is foundational to informed decision-making and has the potential to substantially impact patient care. These findings from the LIGHTHOUSE study showed high reader agreement in interpreting POSLUMA PET/CT scans among a patient population of men with unfavorable intermediate- to very high-risk prostate cancer prior to initial therapy. The high reproducibility of reader results across all regions is clinically valuable, with the potential to influence patient management prior to surgery for patients with newly diagnosed disease.”

“We are pleased to present these reader interpretation results from the Phase 3 LIGHTHOUSE trial at SNMMI’s 2023 Annual Meeting,” said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. “In designing the POSLUMA image interpretation training, we drew upon Blue Earth Diagnostics’ proven expertise and experience in designing PET image interpretation programs and training for our first commercialized product, Axumin® (fluciclovine F 18). Newly FDA-approved POSLUMA represents a new class of purposely engineered, high-affinity PSMA-targeted PET

radiopharmaceuticals based on novel radiohybrid technology. It is labeled with the radioisotope ^{18}F to provide readily available patient access and leverage the high image quality of ^{18}F-labeled PSMA PET imaging to facilitate detection of disease. In a post-hoc Phase 3 analysis, as well as in preclinical and Phase 1 studies, POSLUMA demonstrated low urinary bladder activity, providing the potential for enhanced image evaluation in the prostate and regions near the ureters for patients with prostate cancer."

The findings presented at SNMMI discussed inter- and intra-reader agreement for the interpretation of POSLUMA PET scans. Overall agreement between three blinded readers who received identical training was assessed for 352 evaluable PET scans; in addition, regional agreement was assessed for the prostate/prostate bed, pelvic lymph nodes, and other (extra-pelvic) sites (lymph nodes outside pelvis, soft tissue/parenchyma, and bones). Intra-reader agreement was based on a sample of 70 (20%) randomly selected scans and consisted of re-reads 4 weeks following the initial reads. The overall inter-reader agreement for POSLUMA PET/CT in 352 evaluable scans was ≥95% across pair-wise, inter-reader comparisons, with the highest agreement seen in the prostate/prostate bed region (also ≥95%). Overall intra-reader agreement was ≥96% for each reader. It should also be noted that the interpretation of POSLUMA PET in patients with suspected prostate cancer recurrence may differ depending on imaging readers, particularly in the prostate/prostate bed region.

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 POSLUMA 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] and at the ASCO Genitourinary Cancers Symposium (ASCO GU) in February 2023.[2]

The findings were discussed in an oral presentation at SNMMI 2023 on June 27, 2023, "Inter- and intra-reader reproducibility of ^{18}F-rhPSMA-7.3 PET interpretation in patients with newly diagnosed prostate cancer: Results from a phase 3, prospective, multicenter study (LIGHTHOUSE)," by Phillip H. Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz. Full session details and the abstract are available in the SNMMI online program here.

About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)

Radiohybrid Prostate-Specific Membrane Antigen (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 imaging isotopes for PET imaging, or with therapeutic isotopes for therapeutic use – providing the potential for creating a true theranostic technology. 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 sublicensed the therapeutic application to its sister company Blue Earth Therapeutics. Blue Earth Diagnostics received U.S. Food and Drug Administration approval for its radiohybrid PET diagnostic imaging product for use in prostate cancer in 2023. rhPSMA compounds for potential therapeutic use are investigational and have not received regulatory approval.

About POSLUMA® (flotufolastat F 18)

POSLUMA® (flotufolastat F 18) injection (formerly referred to as ^{18}F-rhPSMA-7.3) is an optimized, targeted radiohybrid diagnostic imaging agent indicated for positron emission tomography (PET) of

prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Precision PET imaging with POSLUMA can help identify the location and extent of prostate cancer, providing clinically valuable information to guide patient management. POSLUMA represents a new class of high-affinity PSMA-targeted PET radiopharmaceuticals based on novel radiohybrid technology and is labeled with the radioisotope ^{18}F to provide readily available patient access and leverage the high image quality of ^{18}F-labeled PSMA PET imaging to facilitate effective detection of disease. POSLUMA was approved by the U.S. Food and Drug Administration in May 2023.

Indication and Important Safety Information About POSLUMA

INDICATION

POSLUMA® (flotufolastat F 18) injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

IMPORTANT SAFETY INFORMATION

- Image interpretation errors can occur with POSLUMA PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of POSLUMA for imaging metastatic pelvic lymph nodes in patients prior to initial definitive therapy seems to be affected by serum PSA levels and risk grouping. The performance of POSLUMA for imaging patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. Flotufolastat F 18 uptake is not specific for prostate cancer and may occur in other types of cancer, in non-malignant processes, and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.
- Risk of Image Misinterpretation in Patients with Suspected Prostate Cancer Recurrence: The interpretation of POSLUMA PET may differ depending on imaging readers, particularly in the prostate/prostate bed region. Because of the associated risk of false positive interpretation, consider multidisciplinary consultation and histopathological confirmation when clinical decision-making hinges on flotufolastat F 18 uptake only in the prostate/prostate bed region or only on uptake interpreted as borderline.
- POSLUMA use contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Advise patients to hydrate before and after administration and to void frequently after administration. Ensure safe handling to minimize radiation exposure to the patient and health care providers.
- The adverse reactions reported in ≥0.4% of patients in clinical studies were diarrhea, blood pressure increase and injection site pain.
- Drug Interactions: androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of flotufolastat F 18 in prostate cancer. The effect of these therapies on performance of POSLUMA PET has not been established.

To report suspected adverse reactions to POSLUMA, call 1-844-POSLUMA (1-844-767-5862) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full POSLUMA prescribing information is available at www.posluma.com/prescribing-information.pdf.

Indication and Important Safety Information About Axumin

INDICATION
Axumin® (fluciclovine F 18) injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

IMPORTANT SAFETY INFORMATION

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation, is recommended.
- Hypersensitivity reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in ≤ 1% of subjects during clinical studies with Axumin. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full Axumin prescribing information is available at https://www.axumin.com/prescribing-information.pdf.

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]Chapin BF, LIGHTHOUSE Study Group. 134: Diagnostic performance and safety of ^{18}F-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.
[2]Chapin BF, on behalf of Koontz BF, LIGHTHOUSE Study Group. Detection of true positive M1 lesions by ^{18}F-rhPSMA-7.3 PET in newly diagnosed prostate cancer: Results from the phase 3 prospective LIGHTHOUSE study. ASCO Genitourinary Cancers Symposium (ASCO GU). San Francisco, Calif: https://meetings.asco.org/abstracts-presentations/217100, 2023.

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