PRESS RELEASE

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Blue Earth Diagnostics Announces Agreement with Siemens Healthineers to Share PET Imaging Agent POSLUMA® (Flotufolastat F 18) Clinical Data to Support AI-based Algorithms Development

–Includes data from Phase 3 LIGHTHOUSE trial evaluating POSLUMA in newly diagnosed prostate cancer–

MONROE TOWNSHIP, N.J., and OXFORD, UK, May 8, 2024 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced the signing of a non-exclusive data-sharing agreement with Siemens Healthineers for anonymized POSLUMA® (flotufolastat F 18) injection (formerly known as ^{18}F-rhPSMA-7.3) clinical data and images from Blue Earth Diagnostics' Phase 3 LIGHTHOUSE trial in newly diagnosed prostate cancer. Siemens Healthineers plans to evaluate the data to enhance its analytics and artificial intelligence (AI)-based algorithms for prostate cancer image quantification and interpretation across its advanced PET/CT imaging software. ^{18}F-flotufolastat is an optimized, high-affinity radiohybrid (rh) Prostate-Specific Membrane Antigen-targeted agent approved in the United States 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.

"Blue Earth Diagnostics is committed to helping men with prostate cancer across the care continuum, and we recognize the importance of AI in advancing healthcare," said David Gauden, D.Phil., Chief Executive Officer, Blue Earth Diagnostics. "AI-based algorithms have the potential to streamline the PET/CT analytical workflow for hospitals and imaging centers by efficiently providing physicians with information critical to patient management and care. Blue Earth Diagnostics has a long-standing relationship with Siemens Healthineers, a leading medical technology company pioneering breakthroughs in healthcare."

Dr. Gauden continued, "We are excited to provide these anonymized POSLUMA data from our LIGHTHOUSE trial, for use in enhancing the Siemens Healthineers *syngo*.via platform. We also plan to make analytical data from the Phase 3 SPOTLIGHT trial of POSLUMA available in the future. POSLUMA represents a new class of high-affinity PSMA-targeted radiopharmaceuticals based on novel radiohybrid technology, and provides physicians with clinically useful information based on its performance at low PSA levels, PSMA binding and low urinary bladder activity. Our product is included in nationally recognized clinical oncology guidelines for prostate cancer, alongside and for all the same categories as the other currently FDA-approved PSMA PET radiopharmaceuticals, and covered by the vast majority of insurance plans. POSLUMA is labeled with the radioisotope fluorine-18 (^{18}F) to leverage high image quality and to enable broad, readily available geographic access for patients via the manufacturing and distribution network of our commercial U.S. manufacturer and distributor, PETNET Solutions Inc, A Siemens Healthineers Company."

"We believe that the LIGHTHOUSE trial data will be enormously helpful in tailoring our AI technology to support the quantification and clinical interpretation of POSLUMA PET/CT images and are pleased to collaborate with Blue Earth Diagnostics on this data-sharing agreement," said Bruce Spottiswoode, Ph.D., Director, Clinical Applications Research, Siemens Healthineers. "The neural networks we are using have been shown to learn radiotracer-specific PET uptake, and we expect them to more efficiently identify clinically relevant features in ^{18}F-flotufolastat images."

The LIGHTHOUSE clinical trial (NC04186819) was an open-label, prospective, Phase 3, multi-center, single-dose, imaging study investigating the safety and diagnostic performance of POSLUMA PET imaging in men with newly diagnosed unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer. The study enrolled 356 patients at clinical sites in the United States and Europe. The SPOTLIGHT study (NCT04186845) was an open-label, prospective, Phase 3, multi-center, single-dose, imaging study investigating the safety and efficacy of POSLUMA PET imaging in men with suspected prostate cancer recurrence. The study enrolled 391 patients at clinical sites in the United States and Europe.

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.

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.

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.

POSLUMA is a registered trademark of Blue Earth Diagnostics Ltd.

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