PRESS RELEASE

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Blue Earth Diagnostics Announces CMS Transitional Pass-Through Payment Reimbursement Code for POSLUMA® (Flotufolastat F 18) Injection, Effective October 1, 2023

– First PSMA-targeted PET imaging agent with radiohybrid technology for prostate cancer was FDA-approved in May 2023 –

– POSLUMA is included in national prostate cancer guidelines and commercially available through an established network of 36 radiopharmacies across the United States –

MONROE TOWNSHIP, NJ, and OXFORD, UK, September 26, 2023 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced that its optimized radiohybrid (rh) Prostate-Specific Membrane Antigen (PSMA)-targeted PET imaging agent, POSLUMA® (flotufolastat F 18) injection (formerly referred to as ^{18}F-rhPSMA-7.3), has been granted Transitional Pass-Through payment status for diagnostic radiopharmaceutical reimbursement by the Centers for Medicare & Medicaid Services (CMS), effective October 1, 2023. CMS grants Pass-Through status to certain new and innovative drugs, to enable broad access for Medicare beneficiaries. Transitional Pass-Through payment enables CMS to provide separate payment for the diagnostic radiopharmaceutical in addition to the associated PET/CT scan, when used with POSLUMA in the hospital-based outpatient setting. 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.

PSMA-targeted PET agents are recognized by national clinical oncology guidelines as effective first-line imaging tools for patients with newly diagnosed and recurrent prostate cancer due to their sensitivity and specificity when compared to conventional imaging. 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 help facilitate effective detection of disease. Precision PET imaging with POSLUMA can provide clinically valuable information to guide patient management for men with prostate cancer, including those with unfavorable intermediate-risk disease, prior to initial therapy, and can reveal nodal and metastatic (M1) disease at initial staging. In the recurrence setting, POSLUMA demonstrated impressive detection rates (% PET positivity) even at low PSA levels. For example, POSLUMA demonstrated a detection rate of 64% (77/121) in men with a PSA <0.5 ng/mL.

“We are very pleased that CMS has granted Pass-Through status for POSLUMA, as it increases patient access to our innovative product to inform patient management,” said David E. Gauden, D.Phil., Chief Executive Officer of the Company. “POSLUMA provides physicians with high-quality diagnostic information based on its diagnostic performance even at low PSA levels, high-affinity PSMA binding and potential for low urinary bladder activity. Blue Earth Diagnostics has a world-class franchise in prostate cancer imaging radiopharmaceuticals, with two FDA-approved, commercially available ^{18}F-labeled PET

imaging agents for prostate cancer. Blue Earth Diagnostics is strongly positioned to help physicians expand informed management and treatment options for men with prostate cancer across the care continuum."

Since FDA approval in May 2023, POSLUMA is available across the United States from 36 radiopharmacies in the reliable national network of our commercial U.S. manufacturer and distributor, the largest U.S. manufacturer of PET imaging agents. Additionally, POSLUMA has recently been added to nationally recognized clinical oncology guidelines for prostate cancer, alongside and for all the same categories as the other currently FDA-approved PSMA PET radiopharmaceuticals.

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.

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.

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