PRESS RELEASE

This press release is for U.S. audiences only

Blue Earth Diagnostics and PETNET Solutions Inc, A Siemens Healthineers Company, Announce U.S. Commercial Availability of POSLUMA® (Flotufolastat F 18) Injection for PET Imaging of Prostate Cancer

– POSLUMA is now commercially available in multiple U.S. radiopharmacies, with nationwide availability by end of June 2023 –

MONROE TOWNSHIP, N.J., OXFORD, UK, & MALVERN, Pa., June 21, 2023 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, and PETNET Solutions Inc, A Siemens Healthineers Company, today announced the commercial availability of POSLUMA® (flotufolastat F 18) in the United States. POSLUMA (formerly referred to as to as ^{18}F-rhPSMA-7.3) is an optimized, high-affinity radiohybrid (rh) Prostate-Specific Membrane Antigen (PSMA)-targeted PET imaging agent. It 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. POSLUMA was approved by the U.S. Food and Drug Administration on May 25, 2023.

POSLUMA is now commercially available through multiple radiopharmacies of PETNET Solutions, the primary manufacturer and commercial distributor for Blue Earth Diagnostics in the United States. By the end of June 2023, commercial production across the country will be underway at the 31 PETNET radiopharmacies Blue Earth Diagnostics included in its New Drug Application for POSLUMA, marking a record number of sites authorized for the manufacturing of a radiopharmaceutical upon its initial FDA approval. Additional PETNET sites are expected to manufacture POSLUMA before the end of the summer.

“We are pleased to make POSLUMA widely available across the United States for use in men with newly diagnosed or suspected recurrence of prostate cancer, and hope that this will make a real difference to physicians and their patients,” said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics Ltd. “Our product introduction plan for POSLUMA includes practical education programs for physicians and staff at imaging centers to educate them on the appropriate use of POSLUMA, including image acquisition and reader training programs to help ensure the best information is available to inform patient care. In addition, we are actively communicating with Medicare carriers, Medicare Advantage Plans, private insurers and radiology benefit managers to help them understand the utility and value of POSLUMA, so that they will cover these procedures appropriately.”

Dr. Gauden continued, “It is an ongoing pleasure to continue working with PETNET Solutions. We have a long-standing, productive relationship based on our seven-year success with Axumin® (fluciclovine F 18). Our companies share a passion for PET molecular imaging, and for providing imaging tools to help inform the management of patients across the prostate cancer care continuum.”

"As the main manufacturer and distributor of POSLUMA to imaging centers in the United States, PETNET Solutions is proud to continue our longstanding commercial relationship with Blue Earth Diagnostics, which began in 2015 when we became a commercial supplier of Axumin," said Barry Scott, Head of PETNET Solutions Inc. "With our large national network of cyclotron-equipped radiopharmacies, we are well-positioned to provide broad access to POSLUMA, as well as a wide range of other novel PET biomarkers that facilitate precision medicine for healthcare providers across the country."

Blue Earth Diagnostics and PETNET Solutions welcome visitors to the upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in Chicago, June 24-27, 2023, to visit their exhibit booths. Blue Earth Diagnostics is at Booth 6025 and PETNET Solutions is at Booth 6075.

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 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.

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.

About Siemens Healthineers AG

Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) pioneers breakthroughs in healthcare. For everyone. Everywhere. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers and its regional companies are continuously developing their product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostics, image-guided therapy, in-vivo diagnostics, and innovative cancer care. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care. In fiscal 2022, which ended on September 30, 2022, Siemens Healthineers, which has approximately 69,500 employees worldwide, generated revenue of around €21.7 billion and adjusted EBIT of almost €3.7 billion. Further information is available at www.siemens-healthineers.com.

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