PRESS RELEASE

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Blue Earth Diagnostics Highlights Presentations on POSLUMA® (Flotufolastat F 18), Axumin® (Fluciclovine F 18) and Investigational ^{18}F-Flotufolastat/^{18}F-rhPSMA-7 at Upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

MONROE TOWNSHIP, N.J. and OXFORD, UK, May 29, 2024 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced upcoming presentations by its collaborators at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, to be held June 8 to 11, 2024, in Toronto, Canada. POSLUMA® (formerly referred to as ^{18}F-rhPSMA-7.3) is approved and 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. Axumin® is approved and indicated for PET imaging in men with suspected prostate cancer recurrence based on elevated PSA levels following prior treatment.

"We are pleased that our collaborators will be sharing important scientific information about POSLUMA, Axumin and investigational experience with ^{18}F-flotufolastat with the imaging community at SNMMI," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "Two presentations relate to the use of POSLUMA and ^{18}F-flotufolastat and the effects of urinary bladder activity on imaging quality. Results from a head-to-head study to be presented by Dr. Isabel Rauscher of the Technical University of Munich examine parameters of PET imaging between ^{18}F-flotufolastat and ^{68}Ga-PSMA-11 in primary prostate cancer, and a presentation by Dr. Ismaheel Lawal will discuss interim results from a study at Emory assessing PET imaging quality with and without the diuretic furosemide in patients with biochemical recurrence of prostate cancer (BCR). Dr. Nadine Mallak of Oregon Health and Science University will present interim results from an ongoing study of the use of Axumin in PSMA/PET-negative BCR patients, and Dr. Rauscher will also describe clinical experience with ^{18}F-rhPSMA-7 and ^{18}F-flotufolastat PET in salvage therapy planning for BCR."

Details of selected oral and poster presentations by Blue Earth Diagnostics collaborators are listed below. Presentations noted by "*" discuss results of experiences with an investigational agent for which the safety and efficacy have not been established by the FDA.

<u>POSLUMA (flotufolastat F 18), investigational ^{18}F-flotufolastat and ^{18}F-rhPSMA-7</u>

DATE:	**Sunday, June 9, 2024**
Title:	**Impact of forced diuresis with furosemide in the evaluation of biochemical recurrence of prostate cancer with ^{18}F-rhPSMA 7.3 PET/CT: Interim analysis of an ongoing prospective trial**
Presenter:	Ismaheel Lawal, MD, PhD, Resident Physician, Department of Radiology and Imaging Sciences, Emory University, Atlanta Ga.
Session Title:	MTA05 POPs/Meet the Author: Oncology: Clinical Therapy & Diagnosis 1

Session Type: Poster presentation
Session Time: 5:00 – 6:15 PM ET
Abstract ID.: 241368

DATE: **Sunday, June 9, 2024**
Title: ***Evaluation of qualitative and quantitative PET parameters in primary prostate cancer patients: double-match comparison of ^{18}F-flotufolastat and ^{68}Ga-PSMA-11-PET**
Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany
Session Title: MTA05 POPs/Meet the Author: Oncology: Clinical Therapy & Diagnosis 1
Session Type: Poster presentation
Session Time: 5:00 – 6:15 PM ET
Abstract ID.: 241424

DATE: **Saturday, June 8, 2024**
Title: ***^{18}F-rhPSMA-7 and ^{18}F-flotufolastat PET-guided salvage radiotherapy in recurrent prostate cancer**
Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany
Session Title: Prostate Cancer: Focus on Imaging
Session Type: Oral presentation
Session Time: 3:30 – 4:45 PM ET
Presentation: 3:35 – 3:45 PM ET
Abstract ID.: 241112

Axumin (fluciclovine F 18)

DATE: **Sunday, June 9, 2024**
Title: **Role of ^{18}F-fluciclovine PET/CT in patients with biochemical recurrence of prostate cancer and a negative PSMA PET/CT: interim results from a prospective trial**
Presenter: Nadine Mallak, MD, Associate Professor, Department of Diagnostic Radiology | Molecular Imaging & Therapy, Body Imaging Director, PET/MRI, Clinical, Oregon Health and Science University, Portland, Ore.
Session Title: MTA05 POPs/Meet the Author: Oncology: Clinical Therapy & Diagnosis 1
Session Type: Poster presentation
Session Time: 5:00 – 6:15 PM ET
Abstract ID.: 241835

Blue Earth Diagnostics invites participants at the 2024 SNMMI Annual Meeting to attend the presentations above and to visit the Company at Exhibit Booth 1639. The Company is hosting a Satellite Symposium, “Let’s Talk about POSLUMA®,” which will discuss the most recent innovations in PSMA-PET imaging for prostate cancer. It will feature invited speakers Sean Collins, MD, PhD, Professor, Georgetown University Hospital, and Elizabeth Hawk, MD, PhD, DABNM DABR, University of California San Diego, and be moderated by Todd Cohen, MD, VP of Medical Affairs, Blue Earth Diagnostics, Inc. The symposium will be held on Sunday, June 9, 2024, from 11:15 AM – 12:15 PM ET in the Toronto Convention Center, Room 701A, South Building – 700 Level. Blue Earth Diagnostics also has a Medical

Affairs information booth at SNMMI, where attendees can learn about the Company's clinical research. For full session details and scientific presentation lists, please see the SNMMI online program here.

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.

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.

Axumin and POSLUMA are registered trademarks of Blue Earth Diagnostics Ltd.

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