

#### PRESS RELEASE

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# Blue Earth Diagnostics Reinforces Leadership in Prostate Cancer Imaging and Highlights Expanding Pipeline at Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2025

**Boston, MA, U.S., June 18, 2025** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative positron emission tomography (PET) radiopharmaceuticals, today announced presentations at the upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, to be held June 21 to 24, 2025, in New Orleans, LA.

The company will unveil new clinical data on its prostate-specific membrane antigen (PSMA)-targeted PET agent and share clinical results that demonstrate potential applications of <sup>18</sup>F -fluciclovine in detection of multiple myeloma<sup>\*</sup> and for patients with negative PSMA scans. "Physicians must be equipped with accurate, actionable molecular imaging to guide more informed clinical decisions," said Marco Campione, President and CEO of Blue Earth Diagnostics. "At SNMMI, we look forward to sharing new analyses and scientific information about POSLUMA<sup>®</sup> and Axumin<sup>®</sup> with the molecular imaging community – highlighting our commitment to delivering innovative solutions for improved patient care."

Blue Earth Diagnostics will be presenting seven abstracts around POSLUMA at SNMMI, including an analysis on the prognostic value of baseline <sup>18</sup>F-flotufolastat PET bone tumor metrics for the occurrence of severe hematologic toxicity in patients with metastatic castration-resistant prostate cancer (mCRPC) treated with <sup>177</sup>Lu-PSMA-I&T.

The Company will also present clinical data around Axumin, highlighting the role of <sup>18</sup>F-fluciclovine PET/CT in patients with biochemical recurrence of prostate cancer and a negative PSMA PET/CT, and potential applications in multiple myeloma.

Blue Earth Diagnostics invites participants at the 2025 SNMMI Annual Meeting to attend the presentations below and to visit the Company at Exhibit Booth 1513.

# POSLUMA (flotufolastat F 18)

DATE: Sunday, June 22, 2025

Title: Impact of Baseline 18F-Flotufolastat PET Bone Tumor Volume for Prognosticating Severe Hematologic Toxicity in Patients with Metastatic Castration-Resistant Prostate Cancer Receiving 177Lu-Labeled PSMA-Targeted Radioligand Therapy

Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany
Session Type: Oral presentation
Session Time: 5:00 – 5:30 PM CT
Abstract ID.: 251321



# DATE: Sunday, June 22, 2025

Title: Prognostic 18F-Flotufolastat PET Parameters for Outcome Assessment of 177Lu-labeled PSMAtargeted Radioligand Therapy in Metastatic Castration-resistant Prostate Cancer Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany Session Type: Poster presentation Session Time: 5:30 – 6:15 PM CT Abstract ID.: 1324

# DATE: Sunday, June 22, 2025

Title: Follow-up 18F-Flotufolastat PET after negative baseline PET in Patients with Suspected Biochemical Recurrence of Prostate Cancer after Radical Prostatectomy Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany Session Type: Poster presentation Session Time: 5:30 – 6:15 PM CT Abstract ID.: 1319

#### DATE: Sunday, June 22, 2025

Title: 18F-Flotufolastat PET/MRI in Suspicious Prostate Cancer: Correlation with Histopathological Biopsy Results Presenter: Nicola Gabler, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany Session Type: Poster presentation Session Time: 5:30 – 6:15 PM CT Abstract ID.: 1318

DATE: Sunday, June 22, 2025BD

Title: Real-World Experience on the Diagnostic Efficacy of 18F-Flotufolastat PET/CT in Preoperative N-Staging as Assessed by Readers of Varying Experience Levels

Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany
Session Type: Poster presentation
Session Time: 5:30 – 6:15 PM CT
Abstract ID.: 1457

# DATE: Sunday, June 22, 2025

# Title: Impact of PSMA-PET based eligibility criteria using 18F-rhPSMA-7.3 (Flotufolastat) on outcome of Lutetium PSMA radioligand therapy

Presenter: Sonia Grigorascu, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany
Session Type: Poster presentation
Session Time: 5:30 – 6:15 PM CT
Abstract ID.: 251150



# DATE: Sunday, June 22, 2025 Title: Prognostic Value of 18F-rhPSMA-7.3 (Flotufolastat-F18) PET Using Visual RECIP During Taxanebased Chemotherapy in Prostate Cancer Presenter: Isabel Rauscher, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Markt Schwaben, Germany Session Type: Poster presentation Session Time: 5:30 – 6:15 PM CT Abstract ID.: 1821

Axumin (fluciclovine F 18) and investigational <sup>18</sup>F-fluciclovine DATE: Sunday, June 22, 2025 Title: 18F-Fluciclovine PET/CT detects more lesions with higher quantitative PET parameters than 18F-FDG PET/CT in multiple myeloma\* Presenter: Liza Lindenberg, M.D., Associate Research Physician, National Cancer Institute, Molecular Imaging, Bethesda, Maryland Session Type: Poster presentation Session Time: 5:30 – 6:15 PM CT Abstract ID.: 251312

# DATE: Monday, June 23, 2025

Title: Do racial differences impact salvage radiotherapy outcomes for prostate cancer recurrence? Presenter: Ismaheel Lawal, Senior Research Fellow, Emory University, Department of Radiology and Imaging Sciences, Atlanta, Georgia Session Type: Poster presentation Session Time: 12:30 – 1:15 PM CT Abstract ID.: 251471

DATE: Tuesday, June 24, 2025 Title: Role of 18F-Fluciclovine PET/CT in patients with biochemical recurrence of prostate cancer and a negative PSMA PET/CT Presenter: Nadine Mallak, M.D., Associate Professor, Oregon Health and Science University, Department of Diagnostic Radiology Molecular Imaging & Therapy, Body Imaging Director, PET/MRI, Clinical, Portland, Oregon Session Type: Poster presentation Session Time: 9:30 – 9:40 AM CT Abstract ID.: 251638

\*<sup>18</sup>F -fluciclovine is not indicated for multiple myeloma and this represents investigational use of this product.

For full session details and scientific presentation lists, please see the SNMMI online program.

# **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 portfolio encompasses a variety of disease states, including oncology. Blue Earth Diagnostics is committed to the timely development and commercialization of precision radiopharmaceuticals for potential use in diagnostic imaging. For more information, please visit: www.blueearthdiagnostics.com.

# **About Bracco Imaging**

Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. The Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Bracco Imaging has approximately 3,800 employees and operates in more than 100 markets globally. Bracco Imaging has a well-skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. R&D activities are in four centers based in Italy, Switzerland, the United Kingdom and the United States. To learn more about Bracco Imaging, visit <u>www.bracco.com</u>.

POSLUMA and Axumin are registered trademarks of Blue Earth Diagnostics.

# U.S. Indication and Important Safety Information About POSLUMA

# INDICATION

POSLUMA<sup>®</sup> (flotufolastat F 18) injection is indicated for positron emission tomography (PET) of prostatespecific 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. Longterm 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 <u>www.fda.gov/medwatch</u>.

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

# U.S. Indication and Important Safety Information About Axumin

# INDICATION

Axumin<sup>®</sup> (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 www.axumin.com/prescribing-information.pdf.

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