



PRESS RELEASE

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Blue Earth Diagnostics Highlights Presentations on POSLUMA® (Flotufolastat F 18) in Prostate Cancer at Upcoming ASTRO Annual Meeting

MONROE TOWNSHIP, NJ, and OXFORD, UK, September 24, 2024 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced presentations on POSLUMA® (flotufolastat F 18) injection (formerly known as ¹⁸F-rhPSMA-7.3) at the upcoming American Society for Therapeutic Radiology and Oncology (ASTRO) 2024 Annual Meeting, to be held in Washington, DC, from September 29 – October 2, 2024. 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.

“PET imaging with POSLUMA can reveal clinical information crucial to decision-making for men with prostate cancer, and we are excited to share new results with the radiation oncology community at ASTRO,” said Marco Campione, Chief Executive Officer of Blue Earth Diagnostics. “Presentations by our collaborators include additional results from the completed Phase 3 SPOTLIGHT study, which evaluated POSLUMA in recurrent prostate cancer, and results from an investigator-initiated study of POSLUMA PET and MRI in recurrent disease. Blue Earth Diagnostics will also host an Industry-Expert Theater event, ‘Let’s Talk About POSLUMA® (flotufolastat F 18)’.”

Details of selected oral and poster presentations by Blue Earth Diagnostics and its collaborators are listed below.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Sunday, September 29, 2024

Oral presentation

Title:	A Prospective Pilot Study Investigating ¹⁸F rhPSMA-7.3 PET/MRI to Detect Disease and Guide Radiotherapy Planning in Patients with Biochemically Recurrent Prostate Cancer Post-Prostatectomy
Presenter:	Devaki Shilpa Surasi, MD, MD Anderson Cancer Center, Houston, Texas
Session Type	Oral
Session Title:	QP 01 – GU 4: GU Quick Pitch
Session Time:	8:00 – 9:00 AM ET
Presentation Time:	8:50 – 9:00 AM ET
Location:	Room 207 B
Presentation No.:	1005

Tuesday, October 1, 2024

Poster presentation

Title: **¹⁸F-Flotufolastat Detection Rates in the Pelvis Region for Patients with Prostate Cancer Recurrence after Radical Prostatectomy and PSA Levels <1 ng/mL: Data from the Phase 3 SPOTLIGHT Study**

Presenter: Bridget F. Koontz,* MD, FASTRO, AdventHealth Cancer Institute, Orlando, FL, for the SPOTLIGHT Study Group (*Duke University Medical Center, Durham, NC - affiliation at time of study)

Session Title: PQA 08 - PQA 08 Genitourinary Cancer, Patient Safety, and Nursing/Supportive Care Poster Q&A

Presentation Time: 2:30 – 3:45 PM ET

Location: Hall C

Presentation No.: 3210

Blue Earth Diagnostics invites participants at the 2024 ASTRO Annual Meeting to attend the presentations above and visit the company at Exhibit Booth 1949. Blue Earth Diagnostics is hosting an Industry-Expert Theater event, “Let’s Talk About POSLUMA® (flotufolastat F 18),” which will feature invited speakers Sean Collins, MD, PhD, Professor, Georgetown University Hospital and Elizabeth Hawk, MS, MD, PhD, DABNM, DABR, University of California San Diego, and be moderated by Todd Cohen, MD, Blue Earth Diagnostics, Inc. The event will be held on Sunday, September 29, 2024, from 12:00 PM to 1:00 PM ET, in Theater 1, Exhibit Hall, of the Walter E. Washington Convention Center. Blue Earth Diagnostics also has a Medical Affairs information booth at ASTRO, where attendees can learn about the Company’s clinical research. For full session details and scientific presentation listings, please see the ASTRO online program [here](#).

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 $\geq 0.4\%$ 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 flutufolostat 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 also 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. Visit: www.braccoimaging.com.

POSLUMA is a registered trademark of Blue Earth Diagnostics Ltd.

Contact:

For Blue Earth Diagnostics (U.S.)

Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917

priscilla.harlan@blueearthdx.com

For Blue Earth Diagnostics (UK)

Clare Gidley

Associate Director Marketing and Communications

Tel: +44 (0)1865 784186

clare.gidley@blueearthdx.com

Media

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

mikebeyer@sambrown.com

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