



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 27, 2023 – 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) 2023 Annual Meeting, to be held in San Diego, Calif., from October 1 to 4, 2023. 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 reveals clinical information crucial to decision-making for men with prostate cancer, and we are excited to share further information with the radiation oncology community at ASTRO 2023,” said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. “Phase 3 results from the SPOTLIGHT trial demonstrated the ability of POSLUMA to detect recurrent disease even at low prostate specific antigen (PSA) levels, and Dr. Ashesh Jani’s oral presentation will detail further information about its diagnostic performance at PSA levels <1 ng/mL. Dr. Phillip Kuo will present additional results from the Phase 3 LIGHTHOUSE trial that evaluated POSLUMA performance in newly diagnosed patients having high/very high risk prostate cancer and negative results with conventional imaging. Blue Earth Diagnostics will also host an Industry-Expert Theater event, ‘POSLUMA: Precision PET Imaging that is Truly Revealing’.”

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

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Monday, October 2, 2023

Oral presentation

Title:	Detection Rate of ¹⁸F-rhPSMA-7.3 PET in Patients with Suspected Prostate Cancer Recurrence at PSA Levels <1 ng/mL: Data from the Phase 3 SPOTLIGHT Study
Presenter:	Ashesh B. Jani, MD, FASTRO, Department of Radiation Oncology, Winship Cancer Institute of Emory University, Atlanta, Ga., for the SPOTLIGHT Study Group
Session Type	Oral
Session Title:	SS11 - GU 3 Novel Prognostication Techniques for Prostate Cancer

Presentation Time: 3:30 – 3:37 PM PT
 Location: Room 6 D/E
 Presentation No.: 160

Tuesday, October 3, 2023

Poster presentation

Title: **Diagnostic Performance of ¹⁸F-rhPSMA-7.3 PET in Men with Newly Diagnosed High-risk Prostate Cancer and Negative Conventional Imaging**

Presenter: Phillip H. Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz., on behalf of Gary A. Ulaner, MD, Ph.D., Hoag Family Cancer Institute, Irvine, Calif. and University of Southern California, Los Angeles, Calif., for the LIGHTHOUSE Study Group

Session Title: PQ 06 – Poster Q&A 06 – Session 06 – Genitourinary Cancer, Patient Safety and Nursing

Presentation Time: 2:30 – 3:45 PM PT
 Location: Hall B1
 Presentation No.: 2972

Blue Earth Diagnostics invites participants at the 2023 ASTRO Annual Meeting to attend the presentations above and visit the company at Exhibit Booth 2223. Blue Earth Diagnostics is hosting an Industry-Expert Theater event, “POSLUMA: Precision PET Imaging that is Truly Revealing,” with invited speaker Dr. Nicholas Zouain, Radiation Oncologist, Medical Director of West Florida Radiation Therapy, US Oncology Network, Clearwater, Fla. The event will be held on Sunday, October 1, 2023, from 12:00 PM to 1:00 PM PT, in Theater 1 of the San Diego Convention Center. 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 flutufolastat 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 flutufolastat 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.

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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