PRESS RELEASE

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Blue Earth Diagnostics Highlights Presentations on POSLUMA® (Flotufolastat F 18) in Prostate Cancer at Upcoming 2024 ASCO Genitourinary Cancers Symposium (ASCO GU)

MONROE TOWNSHIP, N.J., and OXFORD, UK, January 16, 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 ^{18}F-rhPSMA-7.3) at the upcoming ASCO GU 2024 Genitourinary Cancers Symposium (ASCO GU). The conference will be held in San Francisco, Calif., from January 25 to 27, 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.

"Presentations at ASCO GU include additional results from the completed Phase 3 SPOTLIGHT study, which evaluated POSLUMA in recurrent prostate cancer and its ability to detect recurrent disease even at low prostate specific antigen (PSA) levels," said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. "Results to be presented by Dr. Przemyslaw Twardowski, MD, will discuss the impact of POSLUMA on treatment plans for men with recurrent disease after curative-intent primary therapy. A presentation by Dr. Benjamin H. Lowentritt, MD, FACS, will speak about the impact of various Standard of Truth methods in evaluating diagnostic PET radiopharmaceuticals, using the SPOTLIGHT trial as a case study. Dr. Zachariah Taylor, DO, will present a Trials in Progress poster for an Investigator Initiated Study which is evaluating the performance of POSLUMA in detecting N1 and M1 disease for newly diagnosed prostate cancer and its impact on clinical management for patients with extraprostatic disease. PET imaging with POSLUMA reveals clinical information crucial to decision-making for men with prostate cancer, and we are excited to share this information with the oncology community at ASCO GU."

Details of the presentations are listed below.

Moderated poster presentation sessions will take place on Thursday, January 25, 2024 at 11:30 a.m. PT, on Level 1, West Hall of the George R .Moscone Convention Center, and also be available On Demand.

Poster Session A: Prostate Cancer
Primary Track Prostate Cancer- Advanced

Title:	**Impact of ^{18}F-flotufolastat PET on management of patients with recurrent prostate cancer: Data from the SPOTLIGHT study.**
Presenter:	Przemyslaw Twardowski, MD, Saint John's Cancer Institute at Providence Saint John's Health Center, Santa Monica, Calif., on behalf of the SPOTLIGHT Study Group.

Abstract: 38
Poster Board #: A17

Title: **Impact of standard-of-truth method on evaluation of a diagnostic PET radiopharmaceutical: Learnings from the phase 3 SPOTLIGHT study.**
Presenter: Benjamin H. Lowentritt, MD, FACS, Chesapeake Urology Research Associates, Baltimore, Md.
Abstract: 39
Poster Board #: A18

Trials in Progress Poster Session A: Prostate Cancer
Primary Track: Prostate Cancer- Advanced

Title: **Role of 18F-flotufolastat PET/CT imaging in men with high-risk prostate cancer following conventional imaging and associated changes in medical management: A phase 3b investigator-initiated trial.**
Presenter: Zachariah Taylor, DO, Main Line Health, Philadelphia, Pa.
Abstract: TPS347
Poster Board #: Q21

Blue Earth Diagnostics invites participants at the ASCO 2024 Genitourinary Cancers Symposium to attend the presentations above. Participants onsite are also invited to visit Blue Earth Diagnostics' booth (#72). For full session details and scientific presentation listings, please see the ASCO GU 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 ≥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 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.

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