PRESS RELEASE

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Blue Earth Diagnostics Highlights POSLUMA® (Flotufolastat F 18) Injection and Investigational ^{18}F-Flotufolastat Presentations at Upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

MONROE TOWNSHIP, N.J. and OXFORD, UK, June 20, 2023 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced upcoming presentations by the Company and collaborators at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, to be held June 24 – 27, 2023, in Chicago, Ill. Presentations on radiohybrid Prostate-Specific Membrane Antigen-targeted POSLUMA® (flotufolastat F 18) injection (formerly referred to as ^{18}F-rhPSMA-7.3) and investigational studies of ^{18}F-flotufolastat are being made at the conference. They include reader reproducibility results from the Phase 3 LIGHTHOUSE trial, a post-hoc analysis of data from the Phase 3 SPOTLIGHT and LIGHTHOUSE clinical trials evaluating the impact of urinary activity on image interpretation and investigational presentations by the Technical University of Munich (TUM) reporting on image acquisition times, effect of fasting on biodistribution and tumor uptake and outcome predictions for radioligand therapy selection. Additionally, the Company will host a satellite symposium, "PSMA PET: Imaging Reimagined," which will discuss the most recent innovations in PSMA-PET imaging for prostate cancer.

NOTE: POSLUMA 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.

Details of selected oral and poster presentations by Blue Earth Diagnostics and its collaborators are listed below. **Presentations noted by "*" below discuss results of investigational studies of an approved product that is not approved by the FDA for the specific use or purpose noted.**

POSLUMA (Flotufolastat F 18)

Tuesday June 27th
Oral presentations

Title:	**Post-hoc analysis of the LIGHTHOUSE and SPOTLIGHT studies to assess the impact of urinary activity on interpretation of ^{18}F-rhPSMA-7.3 PET/CT**
Presenter:	Phillip H. Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz.
Session Title:	Scientific Session SS44 Prostate Cancer – Radiotracers
Location:	S404 abcd
Session Time:	3:05-3:15 PM CT

Program ID: 52

Title: **Inter- and intra-reader reproducibility of ^{18}F-rhPSMA-7.3 PET interpretation in patients with newly diagnosed prostate cancer: Results from a phase 3, prospective, multicenter study (LIGHTHOUSE)**
Presenter: Phillip H. Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz.
Session Title: Scientific Session IS12 Prostate Cancer – Integrated Session
Location: S502 ab
Session Time: 4:20 – 4:30 PM CT
Program ID: 589

Investigational ^{18}F-fotufolastat

NOTE: Poster presentations are available Saturday, June 24, 2023, from 6:00 – 8:00 PM CT and throughout the meeting in the Science Pavilion. Times for Meet the Author sessions are below.

Sunday, June 25th

Title: ***The effect of different acquisition times on image quality and quantification in F18 PSMA PET/CT***
Presenter: Turkay Hekimsoy, Physician, Department of Nuclear Medicine, Technical University of Munich, Klinikum rechts der Isar, Germany
Type: Poster presentation
Session Title: MTA01-A9 Meet the Author: Physics, Instrumentation & Data Sciences
Location: SP Pod 9
Session Time: 11:00 – 11:30 AM CT
Program ID: 699

Monday, June 26th

Title: ***Influence of fasting prior to ^{18}F-rhPSMA-7.3 PET/CT on biodistribution and tumor uptake: Comparison of clinical data from patients with prostate cancer**
Presenter: Thomas Langbein, Scientist, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine, Germany
Type: Poster presentation
Session Title: MTA04-A13 Meet the Author: Oncology Clinical Diagnosis & Therapy
Location: SP Pod 13
Session Time: 11:15 – 11:45 AM CT
Program ID: 1225

Tuesday June 27th

Oral presentation

Title: ***Extension of a ^{68}Ga-PSMA PET-based nomogram for outcome prediction of ^{177}Lu-PSMA radioligand therapy for the use of ^{18}F-rhPSMA-7.3**
Presenter: Isabelle Rauscher, MD, Technical University of Munich, School of Medicine, Klinikum rechts der Isar, Department of Nuclear Medicine
Session Title: Scientific Session SS44 Prostate Cancer – Radiotracers

Type: Oral presentation
Session Time: 2:55-3:05 PM CT
Location: S404 abcd
Program ID: 400

Blue Earth Diagnostics invites participants at the 2023 SNMMI Annual Meeting to attend the presentations above and to visit the Company at Exhibit Booth 6025. The Company is hosting a Satellite Symposium, "PSMA PET: Imaging Reimagined," which will discuss the most recent innovations in PSMA-PET imaging for prostate cancer. Featured speakers from Blue Earth Diagnostics are Eugene J. Teoh, MBBS, MRCP, FRCR, D.Phil., Chief Medical Officer, and Phillip Davis, MD, Vice President Clinical Science. The event will be held on Sunday, June 25, 2023, from 11:15 AM – 12:15 PM CT in E450a (Lakeside). Blue Earth Diagnostics also has a Medical Affairs information booth at SNMMI, where attendees can learn about clinical trials for the Company and its sister company, Blue Earth Therapeutics. For full session details and scientific presentation lists, please see the SNMMI online program here. Information about Blue Earth Therapeutics presence at SNMMI is available 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 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.

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