PRESS RELEASE

For U.S audiences only

Results of POSLUMA® (Flotufolastat F 18) Performance in Recurrent Prostate Cancer After Radical Prostatectomy at Low Prostate Specific Antigen (PSA) Levels Presented at ASTRO

MONROE TOWNSHIP, NJ, and OXFORD, UK, October 1, 2024 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative positron emission tomography (PET) radiopharmaceuticals, today announced results from a post-hoc analysis from the Phase 3 SPOTLIGHT trial (NCT04186845) that investigated the use of POSLUMA® (flotufolastat F 18) PET injection (formerly referred to as ^{18}F-rhPSMA-7.3) in suspected biochemical recurrence of prostate cancer. The analysis examined the detection rate (% positive PET scans) in the pelvis region for SPOTLIGHT patients who had received radical prostatectomy (RP) only (168/389) and with low-very low Prostate Specific Antigen (PSA) levels of < 1 ng/mL (119/168). Results demonstrated 69% and 67% detection rates for POSLUMA in in men with PSA < 1 ng/mL (82/119) and < 0.5 ng/mL (57/85), respectively. The findings were discussed in a moderated poster presentation at the 2024 ASTRO Annual Meeting on October 1, 2024, "*^{18}F-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*, by Bridget F. Koontz,* MD, FASTRO, AdventHealth Cancer Institute, Orlando, FL for the SPOTLIGHT Study Group. (She was affiliated with Duke University Medical Center, Durham, NC, at the time of the study.) Full session details and the abstract are available in the ASTRO online program here.

FDA-approved POSLUMA® (flotufolastat F 18) 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.

"Physicians need actionable information from PSMA PET scans to guide informed clinical management decisions for men with prostate cancer," said Bridget F. Koontz, MD, FASTRO. "This is of particular importance in the pelvis region, the most common site of recurrence. This analysis explored the performance of POSLUMA in the pelvis region for post-prostatectomy men who were likely in the early stages of disease recurrence. Approximately one-third of patients had detectable recurrence in the prostate bed, suggesting that POSLUMA may be useful in identifying recurrence next to the bladder, and help to guide curative salvage therapy."

"Findings presented at ASTRO about POSLUMA detection rates in the pelvis region for men with recurrent prostate cancer reinforce important clinical considerations in selecting a precision diagnostic imaging agent for PSMA PET procedures," said Marco Campione, Chief Executive Officer of Blue Earth Diagnostics. "Activity in the urinary bladder and ureters is a common feature of PSMA PET radiopharmaceuticals, and can potentially obscure tumors and interfere with accurate image

interpretation. A post-hoc analysis of POSLUMA clinical trials demonstrated that urinary activity did not impact image assessment for 96% of patients (682/712) by majority read[1]."

POSLUMA represents a newer class of high-affinity PSMA-targeted PET radiopharmaceuticals based on novel radiohybrid technology and leverages the high image quality of ^{18}F-labeled PSMA PET imaging to help facilitate detection of prostate cancer. It can provide clinically valuable information to guide patient management based on its high-affinity PSMA binding, low urinary uptake and positive performance at very low PSA levels. POSLUMA is included in nationally recognized clinical oncology guidelines for prostate cancer, covered by the vast majority of insurance plans and is readily available for patients across the country through the network of Blue Earth Diagnostics' commercial U.S. manufacturer and distributor, PETNET Solutions Inc, A Siemens Healthineers Company.

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.

[1]Kuo PH, Hermsen R, Penny R, Postem EJ. 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. *Mol Imaging Biol.* 2024 Feb;26(1):53-60. doi: 10.1007/s11307-023-01867-w.

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