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## **Blue Earth Diagnostics Announces Positive Results from Head-to-Head Comparator Study of POSLUMA® (Flotufolastat F 18) and Piflufolastat F 18 Urinary Bladder Radioactivity in Men with Biochemical Recurrence of Prostate Cancer**

**Boston, MA, U.S., February 27, 2026** — 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 the first head-to-head study comparing urinary bladder radioactivity between two prostate-specific membrane antigen (PSMA)-targeted PET radiopharmaceuticals. This prospective, multicenter, intra-patient comparison evaluated urinary radioactivity and lesion detection rates of POSLUMA® (flotufolastat F 18) and piflufolastat F 18 in men with low prostate-specific antigen (PSA) biochemical recurrence (BCR) of prostate cancer following radical prostatectomy.

The study met its primary endpoint, demonstrating statistically significant lower urinary bladder radioactivity with POSLUMA compared with piflufolastat F 18, as measured by mean standardized uptake value (SUV<sub>mean</sub>). Across 55 evaluable patients, median bladder SUV<sub>mean</sub> was 10.9 for POSLUMA and 29.0 for piflufolastat F 18, with a median difference of 15.1 (interquartile range, 8.5–27.0;  $p < 0.001$ ). Lower urinary radioactivity may help optimize image assessment in regions close to the bladder and ureters, where small recurrent prostate cancer lesions can be challenging to distinguish from urinary activity.

Secondary analyses showed higher patient-level and region-level detection rates with POSLUMA compared with piflufolastat F 18, including among patients with very low PSA levels ( $\leq 0.2$  ng/mL). In this subgroup, majority-read patient-level detection rates were 52.4% with POSLUMA and 38.1% with piflufolastat F 18. Detection rates were also higher with POSLUMA in the prostate bed and extra-pelvic regions.

No significant safety concerns were observed for either radiopharmaceutical.

Biochemical recurrence refers to a rising PSA level after surgery in a patient who previously had undetectable PSA and can be an early sign that prostate cancer has returned, even before it is visible on conventional imaging. PET tracers that can help clearly show small areas of recurrent disease at very low PSA levels may support earlier and more informed clinical care decisions<sup>1</sup>.

*“For men who have already undergone surgery for prostate cancer, a rising PSA can be deeply concerning, especially when conventional imaging cannot clearly show whether or where the disease has returned,”* said Dr. Eugene Teoh, Chief Medical Officer of Blue Earth Diagnostics. *“This head-to-head study provides important clinical evidence from a rigorous intra-patient comparison, demonstrating that POSLUMA exhibits significantly lower urinary radioactivity while maintaining meaningful detection capability in men with early biochemical recurrence. Urinary activity can impact image interpretation,*



*which is of particular consideration at very low PSA levels, where precise localization is critical. These results reinforce the role of POSLUMA as a PSMA-PET imaging agent intelligently designed to support confident image assessment in anatomically challenging regions and reflect our continued commitment to advancing molecular imaging through high-quality clinical evidence.”*

*“This rigorous head-to-head study provides high quality evidence that POSLUMA has significantly lower urinary bladder radioactivity compared to piflufolastat F 18, confirming prior studies,”* said Phillip Kuo, Kuo Radiology LLC. *“POSLUMA also exhibited higher detection rates for recurrence compared to piflufolastat F 18, which highlights its potential to improve patient management.”*

Results from Blue Earth Diagnostics’ head-to-head study have been [published](#) in the *European Journal of Nuclear Medicine and Molecular Imaging* and were just presented at the 2026 ASCO Genitourinary Cancers Symposium (ASCO GU), on February 26, 2026, in San Francisco, California.

#### **About the Head-to-Head Comparator Study**

A prospective, multicenter, intra-patient head-to-head comparator study evaluating the urinary bladder radioactivity and lesion detection rates of POSLUMA® (flotufolastat F 18) and piflufolastat F 18 in men with low prostate-specific antigen (PSA) biochemical recurrence (BCR) of prostate cancer following radical prostatectomy. A total of 55 patients were evaluated with BCR and PSA levels  $\leq 0.5$  ng/mL. The study’s primary endpoint was a calculated difference in bladder SUV<sub>mean</sub> as determined by quantification software. Secondary endpoints were detection rate analyses including patient level and subgroups, PSA level, prostate bed and related subregions, and pelvic lymph nodes.

#### **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 portfolio encompasses a variety of disease states, including oncology. Blue Earth Diagnostics is committed to the timely development and commercialization of precision radiopharmaceuticals for potential use in diagnostic imaging. For more information, please visit: [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.com).

#### **About Bracco**

Bracco Group is founded in 1927, operates in the healthcare sector across more than 100 countries and is a recognized global leader in diagnostic imaging. With a workforce of over 3,800 employees and consolidated annual revenues of approximately €2 billion—88% generated from international markets—Bracco demonstrates a strong commitment to innovation by investing around 9% of its reference turnover in Research & Development. These investments are primarily focused on imaging diagnostics and medical devices. The Group holds more than 2,000 active patents worldwide.



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POSLUMA is a registered trademark of Blue Earth Diagnostics.

## **U.S. Indication and Important Safety Information About POSLUMA**

### **INDICATION**

POSLUMA® (flotufolostat 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. Flotufolostat 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 flotufolostat 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](http://www.fda.gov/medwatch).

**Full POSLUMA prescribing information is available at [www.posluma.com/prescribing-information.pdf](http://www.posluma.com/prescribing-information.pdf).**

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**Reference**

<sup>1</sup> Nordquist, L.T., Andrews, J.R., Kuo, P.H. *et al.* An intra-patient contemporaneous comparison of 18F-piflufolastat and 18F-flotufolastat urinary radioactivity and pelvic region detection rates in men with low PSA biochemical recurrence of prostate cancer after radical prostatectomy. *Eur J Nucl Med Mol Imaging* (2026). Online ahead of print. DOI: [10.1007/s00259-025-07732-y](https://doi.org/10.1007/s00259-025-07732-y)

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