The information contained in this template is provided by Blue Earth Diagnostics, Inc. to help ensure communication of POSLUMA® (flotufolastat F 18) efficacy and safety information in accordance with applicable laws, rules, and regulations. This template is for facilities to use at their discretion. There is no requirement that any patient or healthcare provider use POSLUMA in exchange for this information.

Subject Line: **[INSERT FACILITY NAME]** Now Offering POSLUMA® (flotufolastat F 18) injection

Email Body Copy:

Dear **[INSERT RECIEPIENT NAME]:**

We are pleased to let you know that **[INSERT FACILITY NAME]** is now offering POSLUMA® (flotufolastat F 18) injection at our facility located at **[INSERT FACILITY ADDRESS]**.

POSLUMA is a Prostate-Specific Membrane Antigen (PSMA)-targeted PET diagnostic imaging agent indicated for use in men with prostate cancer with PSMA positive lesions with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.[1] For these men, a POSLUMA PET scan can help determine if prostate cancer is present or has spread within the prostate or prostate bed or to other parts of the body.

Prostate cancer is the second leading cause of cancer death in men in the United States. Determining the extent of primary prostate cancer and whether it may have spread is important. Most primary prostate cancer can be successfully treated, but up to 25% of men with primary prostate cancer may have detectable lymph node metastases, which are associated with a risk for recurrence and decreased overall survival. For some patients, the cancer may come back – this is called recurrence. Prostate cancer can recur in up to 40% of patients, which is the reason why these patients are monitored with periodic PSA blood tests. Recurrent disease is typically detected by a rise in PSA level, but often the location and extent of the disease cannot be detected by standard imaging.

A POSLUMA scan is done using a PET/CT scanner in a hospital or imaging facility and typically takes 20 to 30 minutes. PET imaging is usually combined at the same time with computerized tomography (CT) scanning to improve the quality of the images and to help localize abnormalities. Like many diagnostic imaging agents, POSLUMA includes a radioactive element (fluorine-18) which is used in producing images of the body and its internal organs and tissues.

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.

For more information or to talk to a healthcare professional, please contact: **[INSERT FACILITY CONTACT INFORMATION]**

Sincerely,

[FACILITY CONTACT PERSON]

References: 1. POSLUMA. Package insert. Blue Earth Diagnostics Ltd; 2023.