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PRESS RELEASE

CURIUM ANNOUNCES THE SUBMISSION OF ITS MARKETING AUTHORIZATION APPLICATION FOR [^{18}F]-DCFPyL TO THE EUROPEAN MEDICINES AGENCY

- Submission follows the completion of Phase III PYTHON clinical trial of [^{18}F]-DCFPyL for recurrent prostate cancer in Europe in May 2022
- Phase III PYTHON clinical trial results to be presented at the 35th Annual Congress of the European Association of Nuclear Medicine, October 15-19, 2022 in Barcelona, Spain

(Paris – 27 June 2022) – Curium the world's leading nuclear medicine company, today announced the submission of its Marketing Authorization Application for [^{18}F]-DCFPyL to the European Medicines Agency. The submission comes two months after completing its Phase III PYTHON trial of [^{18}F]-DCFPyL and follows two US pivotal trials – OSPREY and CONDOR by Progenics Pharmaceuticals, Inc., a Lantheus company. In the U.S., [^{18}F]-DCFPyL was approved by the FDA in May of 2021 and is commercially available as PYLARIFY® (Piflufolastat F 18 Injection) and sold by Lantheus.

Sakir Mutevelic, MD, MSc, Chief Medical Officer at Curium commented: "The positive results of our Phase III PYTHON clinical trial conducted in Europe reinforce the diagnostic performance of [^{18}F]-DCFPyL in the pivotal OSPREY and CONDOR clinical trials in multiple stages of prostate cancer disease, confirming our belief in [^{18}F]-DCFPyL and the role it will play in helping Curium to redefine the experience of cancer."

Benoit Woessmer, PET Europe Chief Executive Officer at Curium added: "With the completion of the PYTHON clinical trial and the submission of our Marketing Authorization Application to the European Medicines Agency, Curium demonstrates its continued dedication and commitment to developing life-saving diagnostic solutions for cancer patients around the world. With our state-of-the-art PET radiopharmacy network – the largest in Europe, Curium will be ready to make the product available across Europe post approval in order to make an everyday impact on patients and people."

PYTHON Study

The PYTHON Study (NCT04734184) was a Phase III, European, multicenter, prospective cross-over comparison trial, to evaluate and compare the detection rates, impact on patient management and safety profiles between [^{18}F]-DCFPyL and [^{18}F]-Fluorocholine (the current approved and established gold standard for PET/CT imaging of prostate cancer in Europe), in patients with first biochemical recurrence **(BCR)** after initial definitive therapy with curative intent. This study successfully met the primary endpoint.

The details of the PYTHON study and the clinical results will be presented at the 35th Annual Congress of the European Association of Nuclear Medicine, October 15-19, 2022 in Barcelona, Spain.

PYLARIFY® (piflufolastat F 18) Injection

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U.S. Indication

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent 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

Contraindications

None.

Warnings and Precautions

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY imaging. 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 PYLARIFY for imaging of patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Hypersensitivity Reactions

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

Radiation Risks

Diagnostic radiopharmaceuticals, including PYLARIFY, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reactions

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of ≤2% during clinical studies with PYLARIFY. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

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 PYLARIFY in prostate cancer. The effect of these therapies on performance of PYLARIFY PET has not been established.

To report suspected adverse reactions for PYLARIFY, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

For important risk and use information about PYLARIFY Injection, please see **Full Prescribing information**.

About Curium

Curium is the world's largest nuclear medicine company. We develop, manufacture and distribute world-class radiopharmaceutical products to help patients around the globe. Our proven heritage combined with a pioneering approach are the hallmarks to deliver innovation, excellence and unparalleled service.

With manufacturing facilities across Europe and the United States, Curium delivers SPECT, PET and therapeutic radiopharmaceutical solutions for life-threatening diseases to over 14 million patients annually. The name 'Curium' honors the legacy of pioneering radioactive materials researchers Marie and Pierre Curie, after whom the radioactive element curium was named and emphasizes our focus on nuclear medicine. To learn more, visit curiumpharma.com.

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