

PRESS RELEASE

CURIUM ANNOUNCES SUBMISSION OF THE MARKETING AUTHORIZATION APPLICATION FOR PYLCLARI®, AN INNOVATIVE (¹⁸F)-PSMA PET TRACER INDICATED IN ADULTS WITH PROSTATE CANCER TO SWISSMEDIC

(Paris, France – 21 February 2024) – Curium, a world leader in nuclear medicine, announced today that the marketing authorization application for PYLCLARI® (INN: Piflufolastat (¹⁸F) formerly known as (¹⁸F)-DCFPyL) submitted by exclusive Swiss distributor b.e.imaging AG on 31 January 2024 to the Swiss Agency for Therapeutic Products (Swissmedic) has been accepted for evaluation.

PYLCLARI® is indicated for the detection of prostate-specific membrane antigen (PSMA) positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to initial curative therapy
- To localize recurrence of PCa in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent

Prostate cancer is one of the most frequently diagnosed cancers in men in Europe, accounting for around 23 percent of all new cancer cases in 2020 and nearly 10 percent of all deaths due to cancer in men.

Dr. Michel Wullemin, Head of Radiopharmaceuticals at b.e.imaging commented, “b.e.imaging is proud of the submission of the marketing authorization application for PYLCLARI® to Swissmedic ahead of schedule. We are fully dedicated to improving the situation of prostate cancer patients in Switzerland.”

Benoit Woessmer, PET Europe CEO at Curium commented, “The acceptance of the marketing authorization application by Swissmedic for PYLCLARI® is another important milestone for prostate cancer patients in Switzerland. We look forward to providing an improved choice of tools available to physicians for the diagnosis of prostate cancer patients. Importantly, when in full production PYLCLARI® is expected to be the most widely available ¹⁸F-PSMA tracer in Europe.”

The submission to Swissmedic by b.e.imaging AG was based on Curium’s Marketing Authorization Application for (¹⁸F)-DCFPyL submitted to the European Medicines Agency in July 2022. Marketing authorization for PYLCLARI® (also known as (¹⁸F)-DCFPyL) was granted in July 2023 by the European Commission.

b.e.imaging AG currently distributes Curium’s entire suite of SPECT imaging products across Switzerland and has exclusive distribution rights for PYLCLARI® in Switzerland. When authorization is received, PYLCLARI® will be supplied by three of Curium’s European facilities.

For more information about PYLCLARI®: <https://pylclari.com>

In the U.S., Lantheus received approval for [¹⁸F]-DCFPyL, now PYLARIFY® (Piflufolastat F 18 Injection) from the Food and Drug Administration (FDA) in May 2021. It is the #1 PSMA PET Imaging Agent in the U.S. market. The European rights were licensed by Curium from Progenics, a Lantheus company, in 2018.

About Curium

Curium is a world leader in nuclear medicine. 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 www.curiumpharma.com

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About b.e.imaging AG

b.e.imaging is the Swiss affiliate of the bender group (www.bendergruppe.com). The bender group is a family-owned pharmaceutical wholesaler and producer for contrast media and radiopharmaceuticals in Germany, Austria, France and Switzerland. Its focus on radiology and nuclear medicine includes their own developed software solutions as well as generic contrast media, medical devices, and medical education programs. With more than 160 employees we are fully dedicated to the needs of radiology and nuclear medicine in terms of imaging and therapy.