Lantheus Announces FDA Acceptance of NDA for New Formulation for Market-Leading PSMA PET Imaging Agent

Aug 6, 2025

Designed to expand PSMA PET imaging access for patients by increasing batch size by ~50% and enhancing supply resilience
PDUFA date set for March 6, 2026

BEDFORD, Mass., Aug. 06, 2025 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus") (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for a new formulation of its F 18 PSMA imaging agent filed by its affiliate, Aphelion. The FDA has set an action date goal of March 6, 2026 under the Prescription Drug User Fee Act (PDUFA).

This NDA acceptance builds on the success of Lantheus' market-leading PSMA PET imaging agent, PYLARIFY, which has demonstrated high diagnostic performance and meaningful impact on clinical decision making. If approved, we expect that this new formulation will offer an efficacy consistent with the market-leading PSMA PET agent, PYLARIFY, which has demonstrated an 86% median true-positive rate based on three independent readers in a study of patients with recurrent prostate cancer based on rising PSA after therapy.[1]

"We are pleased the FDA accepted Aphelion's NDA for the new piflufolastat F 18 formulation, which we expect will improve patient access due to a significant increase in the number of doses per batch," said Brian Markison, CEO, Lantheus. "This formulation is a natural next step in our commitment to advancing PSMA imaging. There is a growing burden of prostate cancer in the U.S. and a clear need for accurate and early detection. Building on PYLARIFY's proven performance and accuracy, Lantheus is well-positioned for continued leadership in prostate cancer imaging."

This new formulation optimizes the manufacturing process and is expected to increase batch size by ~50%, allowing Lantheus to serve significantly more patients while maintaining the same high standards that has made PYLARIFY the trusted choice for providers. The new formulation increases the radioactive concentration of the agent and has the potential to expand patient access in new geographic locations.

"We have reached a key milestone and delivered on our commitment to advance prostate cancer imaging through sustainable innovation," said Paul Blanchfield, President, Lantheus. "By enhancing the efficiency of production, we expect to improve patient access, streamline operations, and support the broader healthcare system's ability to deliver timely diagnostic imaging."

About Prostate Cancer

In the U.S., prostate cancer is the second most frequently diagnosed cancer and fifth-leading cause of cancer-related deaths among men globally. For 2025, estimates suggest nearly 315,000 new cases and more than 35,000 deaths.[2] Projections indicate a significant increase in prostate cancer incidence, with annual cases expected to nearly double to 2.9 million by 2040.[3] This is largely attributed to aging populations and increased life expectancy, particularly in low- and middle-income countries where healthcare access and early detection may be limited.

About PYLARIFY® (piflufolastat F 18) Injection
PYLARIFY® (piflufolastat F 18) injection (also known as ^{18}F-DCFPyL or PyL) is a fluorinated small molecule PSMA-targeted PET imaging agent that enables visualization of lymph nodes, bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer. For men with prostate cancer, PYLARIFY PET combines the accuracy of PET imaging, the precision of PSMA targeting and the clarity of an F 18 radioisotope for superior diagnostic performance. The recommended PYLARIFY dose is 333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.[3-9]

PYLARIFY has made a profound impact on the lives of patients battling prostate cancer. It is the number one ordered PSMA PET imaging agent in the U.S., and is a proven diagnostic backed by real-world experience, including in over 500,000 scans across 48 states, Puerto Rico and Washington, D.C.

PYLARIFY® (piflufolastat F 18) Injection

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. Please read the accompanying full Prescribing Information also available at PYLARIFY.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential FDA approval of the NDA for a new formulation of piflufolastat F18, the Company’s F-18 based PET imaging agent and statements regarding Lantheus’ expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements may be identified by their use of terms such as “aim,” “designed,” “expect,” “expected,” “will” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements, including our ability to obtain FDA approval for our new formulation of PYLARIFY, to complete the technology transfer across our PET manufacturing facilities network for such new formulation, and to obtain adequate coding, coverage and payment, as well as the risk and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada, Germany, Sweden and Switzerland, Lantheus has been providing radiopharmaceutical solutions for nearly 70 years. For more information, visit www.lantheus.com.

[1]Morris MJ, et al; CONDOR Study Group. Diagnostic Performance of 18F-DCFPyL-PET/CT in Men with Biochemically Recurrent

Prostate Cancer: Results from the CONDOR Phase III, Multicenter Study. Clin Cancer Res. 2021 Jul 1;27(13):3674-3682. doi: 10.1158/1078-0432.CCR-20-4573. Epub 2021 Feb 23. PMID: 33622706; PMCID: PMC8382991.

[2]American Cancer Society. *Cancer Facts & Figures 2025.* Atlanta: American Cancer Society; 2025. Available at https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2025-cancer-facts-figures.html

[3]Harris E. Prostate Cancer Cases Might Rise to 3 Million Globally by 2040. *JAMA.* 2024;331(20):1698. doi:10.1001/jama.2024.6729

[4]PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company.

[5]Data on file. Bedford, MA: Progenics Pharmaceuticals, Inc.; 2024.

[6]Mena E, Lindenberg ML, Turkbey IB, et al. *18*F-DCFPyL PET/CT imaging in patients with biochemically recurrent prostate cancer after primary local therapy. *J Nucl Med*. 2020;61(6):881-889.

[7]Werner RA, Derlin T, Lapa C, et al. *18*F-labeled, PSMA-targeted radiotracers: leveraging the advantages of radiofluorination for prostate cancer molecular imaging. *Theranostics.* 2020;10(1):1-16.

[8]Alipour R, Azad A, Hofman MS. Guiding management of therapy in prostate cancer: time to switch from conventional imaging to PSMA PET? *Ther Adv Med Oncol*. 2019;11:1-14.

[9]Petersen LJ, Zacho HD. PSMA PET for primary lymph node staging of intermediate and high-risk prostate cancer: an expedited systematic review. *Cancer Imaging*. 2020;20(1):10.

Contacts:

Lantheus
Mark Kinarney
Vice President, Investor Relations
978-671-8842
ir@lantheus.com

Melissa Downs
Executive Director, External Communications
646-975-2533
media@lantheus.com

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