



## Lantheus Announces FDA Approval of PYLARIFY TruVu™ (piflufolastat F 18) Injection

Mar 6, 2026

*New formulation of its widely-used U.S. market-leading PSMA PET imaging agent combines the diagnostic performance of PYLARIFY® (piflufolastat F 18) with the potential for larger batches and greater patient availability*

*PYLARIFY TruVu™ is expected to launch in 4Q 2026, with a phased geographic rollout to support a seamless customer transition*

BEDFORD, Mass., March 06, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus") (NASDAQ: LNTX), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the U.S. Food and Drug Administration (FDA) has approved PYLARIFY TruVu (piflufolastat F 18) injection, a new formulation of its F 18 prostate-specific membrane antigen (PSMA) imaging agent. PYLARIFY TruVu is indicated for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

"The FDA approval of PYLARIFY TruVu demonstrates Lantheus' continued commitment to advancing innovation that directly expands patient access to high-quality diagnostic tools," said Mary Anne Heino, Executive Chairperson and CEO, Lantheus. "The availability of PYLARIFY TruVu addresses a key need identified by clinicians – greater access to our market-leading formulation."

PYLARIFY TruVu was submitted for FDA approval via the 505(b)(2) regulatory pathway, allowing for review based upon previously submitted data from two PYLARIFY pivotal studies: OSPREY and CONDOR. The new formulation has the same diagnostic properties and is expected to offer similar safety and effectiveness as PYLARIFY.

Additionally, PYLARIFY TruVu is designed to enhance product stability at higher radioactive concentrations, supporting more efficient manufacturing and distribution. These improvements are expected to increase batch sizes, enabling manufacturing sites with high-energy cyclotrons to reach more patients and serve broader geographic markets. Overall, PYLARIFY TruVu has the potential to enhance supply flexibility and improve operating leverage for the network of PMFs that will manufacture and distribute the product.

"As we continue to innovate and expand our portfolio, ensuring a reliable and uninterrupted supply for our customers remains our top priority," said Dorothy Barr, Senior Vice President, Manufacturing and Technical Operations. "The PYLARIFY TruVu formulation is designed to enhance manufacturing efficiency, strengthen supply chain dependability and ultimately improve the healthcare system's ability to deliver timely, accurate imaging for people with prostate cancer."

PYLARIFY TruVu is expected to be commercially available in the fourth quarter of 2026 and will be introduced on a rolling geographic basis, allowing customers to transition from PYLARIFY to the new formulation with minimal disruption.

"As a community dedicated to improving the lives of people facing prostate cancer, we've seen firsthand how advanced PSMA PET diagnostic tools like PYLARIFY have truly been game changers, providing real-time, highly accurate information that can meaningfully shape treatment decisions," said Gina B. Carithers, President and CEO, Prostate Cancer Foundation. "With prostate cancer incidence expected to rise in the years ahead, it's encouraging to see companies like Lantheus putting patients first and introducing innovations that help ensure timely, precise imaging while keeping pace with growing demand. Access to accurate diagnostics, especially when metastatic or recurrent disease is suspected, can profoundly impact both quality of life and long-term outcomes for people living with prostate cancer."

More than 760,000 people with prostate cancer have received PSMA PET scans with PYLARIFY since the FDA granted approval in May 2021 based on findings from the OSPREY and CONDOR studies.

### **PYLARIFY® Pivotal Data Summary**

The safety and efficacy of PYLARIFY® and PYLARIFY TruVu™ were established based on the PYLARIFY pivotal trials, OSPREY and CONDOR. OSPREY was a phase 2/3 clinical trial of 385 patients. In Cohort A, 252 men with high-risk prostate cancer had evaluable histopathology for determining the diagnostic performance of PYLARIFY in identifying pelvic nodal metastases. OSPREY Cohort A assessed sensitivity, specificity, PPV, and NPV in pelvic lymph nodes and the prostate gland for PSMA-targeted PET with PYLARIFY. The median sensitivity, specificity, PPV and NPV were 38% (26, 51), 96% (94, 99), 77% (62, 92) and 83% (78, 88). Results showed that a PSMA-targeted PET scan with PYLARIFY significantly improved specificity over standard imaging while maintaining comparable sensitivity and delivering high PPV and NPV in men at risk for metastatic prostate cancer prior to initial therapy. Compared to standard imaging, PYLARIFY PET/CT delivered: Significantly higher specificity (97.9%

vs 65.1%), nearly three times the PPV (86.7% vs 28.3%) and similar sensitivity to standard imaging (40.3% vs 42.6%).<sup>1</sup>

CONDOR was a robust, multicenter, phase 3 trial of 208 patients with suspected recurrent or metastatic prostate cancer with negative or equivocal results using standard imaging. The study design assessed correct localization rate (CLR), a metric of diagnostic performance measuring PPV at the patient level enhanced with anatomic lesion matching in patients with biochemically recurrent (BCR) prostate cancer.

CONDOR found that a PSMA-targeted PET scan with PYLARIFY in men with biochemical recurrent prostate cancer achieved the primary endpoint of correct localization rate (CLR): 85%-87% across all 3 readers (lower bound of 95% CI: 78%-80%).<sup>2</sup>

The safety of PYLARIFY was evaluated in 593 clinical patients who were exposed to a single dose of PYLARIFY and was generally well tolerated. The most common adverse reactions reported in  $\leq 2\%$  of patients were headache, dysgeusia and fatigue. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reaction.<sup>3</sup>

### **About Prostate Cancer**

Prostate cancer is the second most common form of cancer affecting men in the U.S. An estimated 1 in 8 men will be diagnosed in their lifetime. The incidence rate for prostate cancer has been increasing since 2014 at a rate of 3% per year overall. For 2026, estimates suggest nearly 334,000 new cases and more than 36,000 deaths. Prostate cancer can be a serious disease and is the second-leading cause of cancer death in men (behind lung cancer), but most men diagnosed with prostate cancer do not die from it. In fact, more than 3.5 million men in the U.S. consider themselves prostate cancer survivors.<sup>4</sup>

### **PYLARIFY TruVu™ (piflufolastat F 18) Injection**

PYLARIFY TruVu™ (piflufolastat F 18) injection (also known as <sup>18</sup>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.<sup>1,2</sup>

PYLARIFY TruVu was developed to build on the success of PYLARIFY®, the number one utilized PSMA PET imaging agent in the U.S. which has been used in over 760,000 scans across 48 states, Puerto Rico and Washington, D.C.<sup>5</sup>

### **INDICATION**

PYLARIFY® (piflufolastat F 18) and PYLARIFY TRUVU™ (piflufolastat F 18) Injection are 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**

#### **WARNINGS AND PRECAUTIONS**

##### **Risk of Image Misinterpretation**

Imaging interpretation errors can occur with PYLARIFY and PYLARIFY TRUVU 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 and PYLARIFY TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY and PYLARIFY TRUVU 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 and PYLARIFY TRUVU 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, is recommended.

##### **Hypersensitivity Reactions**

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

##### **Radiation Risks**

PYLARIFY and PYLARIFY TRUVU, 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  $\leq 2\%$  during clinical studies. 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 and PYLARIFY TRUVU in prostate cancer. The effect of these therapies on performance of PYLARIFY and PYLARIFY TRUVU PET has not been established.

To report suspected adverse reactions for PYLARIFY or PYLARIFY TRUVU, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). Please see the full Prescribing Information for [PYLARIFY](#) and [PYLARIFY TRUVU](#).

### Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as “allowing,” “continue,” “designed,” “enabling,” “enhance,” “ensuring,” “expand,” “expected,” “improve,” “potential,” “transition,” “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. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) our ability to complete the technology transfer across our PET manufacturing facilities (“PMF”) network for PYLARIFY TruVu and to obtain FDA approval for each PMF to manufacture PYLARIFY TruVu in accordance with our planned rollout plan and without disruption to our supply chain; (ii) our ability to obtain adequate coding, coverage and payment, including transitional pass-through payment status, for PYLARIFY TruVu and to have customers adopt PYLARIFY TruVu; (iii) the ability of our PMF network to supply PYLARIFY TruVu to the market; (iv) the ability of PMF sites with high-energy cyclotrons to increase batch sizes or to reach more patients and serve broader geographic markets; (v) the intellectual property protection of PYLARIFY TruVu; and (vi) 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, Switzerland and the United Kingdom, Lantheus has been providing radiopharmaceutical solutions for 70 years. For more information, visit [www.lantheus.com](http://www.lantheus.com).

### Contacts:

Lantheus  
Mark Kinarney  
Vice President, Investor Relations  
978-671-8842  
[ir@lantheus.com](mailto:ir@lantheus.com)

Melissa Downs  
Executive Director, External Communications  
646-975-2533  
[media@lantheus.com](mailto:media@lantheus.com)

Multimedia assets for media are available [here](#).

<sup>1</sup>Pienta KJ, Gorin MA, Rowe SP, et al. A phase 2/3 prospective multicenter study of the diagnostic accuracy of prostate specific membrane antigen PET/CT with 18F-DCFPyL in prostate cancer patients (OSPReY). *J Urol*. 2021;206(1):52-61.

<sup>2</sup>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.

<sup>3</sup>PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company

<sup>4</sup>American Cancer Society. Cancer Facts & Figures 2026. Atlanta: American Cancer Society; 2026. Available at <https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html>

<sup>5</sup>Data on file. Bedford, MA: Progenics Pharmaceuticals, Inc.; 2024.

A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/24fb7ced-261c-4dbb-add2-3739ec1effe7>



## PYLARIFY TruVu™ (piflufolastat F 18) Injection



**PYLARIFY TruVu™ (piflufolastat F 18) Injection, a new formulation of Lantheus' widely-used U.S. market-leading PSMA PET imaging agent that combines the diagnostic performance of PYLARIFY® (piflufolastat F 18) with the potential for larger batches and greater patient availability.**

Source: Lantheus Holdings, Inc.