Lantheus and GE HealthCare Announce Exclusive Licensing Agreement for Prostate Cancer Imaging Agent PYLARIFY® (Piflufolastat F 18) in Japan

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BEDFORD, Mass. and CHICAGO and TOKYO, Sept. 24, 2025 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (NASDAQ: LNTH) and GE HealthCare (NASDAQ: GEHC) today announced an exclusive licensing agreement for GE HealthCare to develop, manufacture, and commercialize Lantheus' piflufolastat F18 (PYLARIFY ® in U.S. market) in Japan for prostate cancer diagnostics and companion diagnostic use. PYLARIFY is used for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.

The agreement includes the transfer of regulatory dossiers, manufacturing competencies and technical support to enable GE HealthCare to drive clinical development in Japan, towards potential regulatory submissions and commercial launch. GE HealthCare will draw on its extensive manufacturing network and R&D expertise following its acquisition in March 2025 of Nihon Medi-Physics Co., Ltd. (NMP), a leading radiopharmaceutical company in Japan.

Prostate cancer is the fourth most common cancer worldwide, with Japan recording the third highest number of cases in the world in 2022, after the U.S. and China.[1]

"This partnership is expected to meaningfully extend the reach of our diagnostic imaging agent in key international markets," said Brian Markison, CEO of Lantheus. "GE HealthCare and NMP's deep regional expertise will enable us to advance the detection and care of prostate cancer and drive significant impact in an important market."

"Bringing targeted PET imaging agents to new geographies supports Lantheus' Purpose to Find, Fight and Follow disease to deliver better patient outcomes," added Jean-Claude Provost, Chief Science Officer at Lantheus. "By aligning with GE HealthCare, we're addressing a critical clinical need in Japan, and helping to lay the foundation for a more personalized approach to prostate cancer detection, diagnosis and monitoring."

"This collaboration represents a strategic advancement for GE HealthCare as we expand our pipeline of radiopharmaceuticals and continue to deliver on our commitment to improving patient access to innovative diagnostics," said Kevin O'Neill, President & CEO of the Pharmaceutical Diagnostics (PDx) segment of GE HealthCare and President of NMP. "Working alongside Lantheus gives us access to one of the best-in-class PET imaging agents that is already approved in the U.S. and in Europe, and if approved locally, could provide clinicians and their patients with a powerful new option for detecting and monitoring prostate cancer."

Under the terms of the agreement, GE HealthCare will pay Lantheus an upfront license fee, development milestones and tiered royalties based on product sales in Japan. The companies will also establish a Joint Steering Committee to oversee development and commercialization activities.

Piflufolastat F 18 (also known as ^{18}F-DCFPyL, PYLARIFY or PYLCLARI™) was FDA-approved in 2021 and is marketed as PYLARIFY. PYLARIFY has made a profound impact on the lives of patients battling prostate cancer and is the number one utilized PSMA PET imaging agent in the U.S. It is a proven diagnostic backed by real-world experience, including in over 500,000 scans across 48 states. In 2023, it was approved in the European Union and is marketed there as PYLCLARI. The European rights were licensed to Curium from Progenics Pharmaceuticals, Inc., a Lantheus company.

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[1] World Cancer Research Fund. https://www.wcrf.org/preventing-cancer/cancer-statistics/prostate-cancer-statistics/

About PYLARIFY® (piflufolastat F 18) Injection

PYLARIFY® (piflufolastat F 18) injection (also known as ^{18}F-DCFPyL or PYLCLARI®) 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.[2,3,4,5,6,7]

PYLARIFY® (piflufolastat F 18) Injection in the 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.

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

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

[4] 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.

[5] 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.

[6] 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.

[7] 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.

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.

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.

About GE HealthCare Technologies Inc.
GE HealthCare is a trusted partner and leading global healthcare solutions provider, innovating medical technology, pharmaceutical diagnostics, and integrated, cloud-first AI-enabled solutions, services and data analytics. We aim to make hospitals and health systems more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected and compassionate care,

while simplifying the patient's journey across care pathways. Together, our Imaging, Advanced Visualization Solutions, Patient Care Solutions and Pharmaceutical Diagnostics businesses help improve patient care from screening and diagnosis to therapy and monitoring. We are a $19.7 billion business with approximately 53,000 colleagues working to create a world where healthcare has no limits.

GE HealthCare is proud to be among 2025 Fortune World's Most Admired Companies™.

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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 "believe," "can," "continues," "plan," "potential," "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. The Company 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) expectations for future clinical trials, the timing and potential outcomes of clinical trials and filings and other interactions with regulatory authorities; (ii) the impact of legislative, regulatory, competitive and technological changes; (iii) GE HealthCare's and Nihon Medi-Physics Co., Ltd.'s ability to successfully launch piflufolastat F 18 as a commercial product in Japan; and (iv) 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).

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