Lantheus Announces Presentations Featuring PYLARIFY (Piflufolastat F 18) Data at the ASCO GU Meeting

February 5, 2025 at 8:30 AM EST

Data highlights PYLARIFY's ability to detect recurrent prostate cancer in patients with low PSA

Real-world evidence of PYLARIFY's effectiveness in prostate cancer being presented

BEDFORD, Mass., Feb. 05, 2025 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (the Company) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, announced piflufolastat F 18 data will be presented at the 2025 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, taking place February 13-15, 2025, in San Francisco, CA.

Presentation details are as follows:

Date & Time: Thursday, February 13, 2025, 11:25 am – 12:45 pm PT and 5:45 PM-6:45 PM PT
Session Number: Poster Session A
Session Title: Prostate Cancer
Title: Early Detection of Recurrent Prostate Cancer Using 18F-DCFPyL PET/CT in Patients with Minimal PSA Levels
Presenter: Ida Sonni, University of California, Department of Radiation Oncology
Poster Number: J8

Date & Time: Thursday, February 13, 2025, 11:25 am – 12:45 pm PT and 5:45 PM-6:45 PM PT
Session Number: Poster Session A
Session Title: Prostate Cancer
Title: The Role of Conventional Imaging and Piflufolastat F18 in Newly-Diagnosed and Recurrent Prostate Cancer Patients: Preliminary Observations from the PYLARIFY Registry
Presenter: Neal Shore, Carolina Urologic Research Center
Poster Number: A19

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.[1-6]

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 400,000 scans across 48 states.

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.

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 Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

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