



Lantheus to Present Piflufolastat F 18 Data at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium

Feb 8, 2023

BEDFORD, Mass., Feb. 08, 2023 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (the Company) (NASDAQ: LNTX), a company committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease, announced it will present piflufolastat F 18 data at the upcoming 2023 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, taking place February 16-18, 2023, in San Francisco, CA.

Piflufolastat F 18 is a PSMA-targeted radiopharmaceutical approved in the U.S. for imaging prostate cancer patients both at the time of initial staging and at disease recurrence.

"Earlier investigation with piflufolastat F 18 PSMA PET/CT in men with biochemically recurrent prostate cancer reported a change in recommended management for nearly two out of three men based on the scan results," said Bela S. Denes, MD, Vice President, Global Medical Affairs, Lantheus. "This study expanded on those findings focusing specifically on the impact and utility of scanning men with very low PSA levels. We look forward to detailing the data at this month's ASCO GU conference."

Presentation details are as follows:

Date & Time: February 16, 2023, 11:30am – 1:00pm; 5:45pm – 6:45pm PT

Session Title: Poster Session A: Prostate Cancer

Title: Changes in planned disease management after piflufolastat F 18 PET/CT in men with biochemically recurrent prostate cancer and low PSA levels: a secondary analysis from the CONDOR study

Presenter: Dr. Frederic Pouliot

Abstract Number: 61

The abstract will be available on meetinglibrary.asco.org February 13.

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 $\leq 2\%$ 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.

For important risk and use information about PYLARIFY Injection, please see [Full Prescribing information](#).

About Lantheus

With more than 65 years of experience in delivering life-changing science, Lantheus is committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. Lantheus is headquartered in Massachusetts and has offices in New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

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Source: Lantheus Holdings, Inc.