Lantheus Presents Data Reinforcing Real-World Clinical Utility of Piflufolastat F 18 PET Scanning in Men with Recurrent Prostate Cancer and Low PSA Levels

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Data presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium Demonstrate Potential Benefits of Piflufolastat F 18 Decision Making on Treatment Plans

BEDFORD, Mass., Feb. 16, 2023 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (the Company) (NASDAQ: LNTH), a company committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease, today presented piflufolastat F 18 data at the 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 US for imaging prostate cancer patients both at the time of initial staging and at disease recurrence. In this study, researchers sought to evaluate the clinical utility of piflufolastat F 18 scanning in men with very low/low PSA levels (< 0.5 ng/mL).

“PYLARIFY has the potential to contribute meaningful and actionable information that can be used to personalize treatment plans in men with low PSA levels,” said Dr. Frederic Pouliot, Hospitalier Universitaire (CHU) de Québec-Université Laval. “The data we presented at ASCO GU emphasize the clinical utility of piflufolastat F 18 to assess the relevance and applicability of intended treatment management plans.”

“We had observed in the CONDOR Phase 3 study of men with biochemically recurrent (BCR) prostate cancer, that nearly two-thirds of patients had their treatment plan altered, attributed to learnings from the scan itself,” said Jean-Claude Provost, MD, Chief Medical Officer, Lantheus. “These data in the subset of men with low PSA levels reinforces the impact and potential role of piflufolastat F 18 in informing patient management decisions in real-world scenarios.”

A summary of the data presented follows:

- In patients with PSA levels below 0.5 ng/mL, changes in intended management occurred in 39.1 percent of cases.
- In 74.1 percent (20/27) of patients with a reported change in management, the initial intended treatment was intensified as a result of the scan images.
- This analysis supports the clinical utility of piflufolastat F18 PET/CT in men with low PSA levels (0.2ng/mL – 0.5 ng/mL)

The abstract, **“**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,” is available on meetinglibrary.asco.org.

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**.

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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