Lantheus Announces Collaboration to Support Prostate Cancer Clinical Development

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Novartis will include PYLARIFY® (piflufolastat F18) in their clinical trials for Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) for the selection of patients with prostate cancer

NORTH BILLERICA, Mass., March 29, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("the Company") (NASDAQ: LNTH), an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find, Fight and Follow serious medical conditions, today announced a strategic collaboration with Novartis to include PYLARIFY® (piflufolastat F18) in prostate cancer clinical trials with Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan).

"The FDA-approval of Novartis' Pluvicto brings hope to patients and is an exciting advancement in the field of radiopharmaceutical oncology," said Mary Anne Heino, President and CEO of Lantheus. "We look forward to collaborating to further explore how PSMA PET imaging agents, like PYLARIFY, may aid in increasing accessibility to PSMA-targeted therapeutics. As always, our goal is to Find, Fight and Follow serious medical conditions and improve patient outcomes."

PYLARIFY, approved by the FDA in May 2021, is the first commercially and widely available prostate-specific membrane antigen (PSMA) PET imaging agent. The collaboration with Novartis directly aligns with Lantheus' strategy to advance cancer precision medicine by enabling partners to use PYLARIFY in prostate cancer therapeutic trials. As part of the agreement with Novartis, Lantheus will provide PYLARIFY for the selection of patients with prostate cancer and Novartis will provide all PYLARIFY related clinical imaging data to Lantheus.

The Company believes the approval of a PSMA-targeted therapeutic for the treatment of adult patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) who have already been treated with other anticancer treatments (androgen receptor pathway inhibition and taxane-based chemotherapy) creates a new addressable market for the use of PSMA PET imaging in patient selection for PSMA-targeted therapy. As a result, the Company estimates the U.S. Total Addressable Market (TAM) for all PSMA PET imaging increases by approximately 30,000 de novo scans per year for this mCRPC patient population. The Company now estimates the TAM to be 250,000 scans, or approximately $1.1 billion, up from its previous estimate of 220,000 scans.

About Prostate Cancer
Prostate cancer is the second most common form of cancer affecting men in the United States -- an estimated one in eight men will be diagnosed with prostate cancer in their lifetimes. The American Cancer Society estimates that in 2022, almost 268,500 new cases of prostate cancer will be diagnosed, and about 34,500 men will die of the disease. Approximately 3.1 million men in the United States currently count themselves as prostate cancer survivors.[1]

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.[2-7]

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 Holdings, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB and an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find Fight and Follow® serious medical conditions. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; PYLARIFY®, a PSMA PET imaging agent for the detection of suspected recurrent or metastatic prostate cancer; PYLARIFY AI™, an artificial intelligence platform that assists in the evaluation of PSMA PET images; TechneLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; AZEDRA® for the treatment of certain rare neuroendocrine tumors; and RELISTOR® for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc. The Company is headquartered in North Billerica, Massachusetts with offices in New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

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 “achieve,” “believe,” “continue,” “current,” “executes,” “future,” “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) our ability to successfully launch PYLARIFY as a commercial product, including (A) our ability to obtain United States Food and Drug Administration (“FDA”) approval for additional positron emission tomography (“PET”) manufacturing facilities (“PMFs”) to manufacture PYLARIFY, (B) the ability of those PMFs to manufacture PYLARIFY, (C) our ability to sell PYLARIFY to customers, and (D) our ability to obtain and maintain adequate coding, coverage and payment for PYLARIFY; (ii) Novartis’ ability to successfully launch PLUVICTO as a commercial product; (iii) the timing and potential outcomes of clinical studies evaluating the use of PYLARIFY with PLUVICTO for the selection of patients with prostate cancer; and (iv) the risks 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), including, but not limited to those related to PYLARIFY.

[1]American Cancer Society. Facts & Figures 2022. American Cancer Society. Atlanta, GA. 2022.

[2]Mena et al. 18 F-DCFPyL PET/CT Imaging in Patients with Biochemically Recurrent Prostate Cancer After Primary Local Therapy J Nucl Med 2020 Jun;61(6):881-889. doi: 10.2967/jnumed.119.234799. Epub 2019 Nov 1.

[3]Alipour et al. Guiding management of therapy in prostate cancer: time to switch from conventional imaging to PSMA PET? Ther

Adv Med Oncol. 2019; 11: 1758835919876828.
[4]Werner et al 18F-Labeled, PSMA-Targeted Radiotracers: Leveraging the Advantages of Radiofluorination for Prostate Cancer Molecular Imaging Theranostics 2020; 10(1):1-16. doi:10.7150/thno.37894.
[5]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):1-8. doi:10.1186/s40644-020-0290-
[6]Tan N, Oyoyo U, Bavadian N, et al. PSMA-targeted radiotracers versus 18F fluciclovine for the detection of prostate cancer biochemical recurrence after definitive therapy: a systematic review and meta-analysis. Radiology. 2020;296:44-55. doi:10.1148/radiol.2020191689
[7]PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company

Contacts:
Mark Kinarney
Senior Director, Investor Relations
978-671-8842
ir@lantheus.com

Melissa Downs
Director, Corporate Communications
646-975-2533
media@lantheus.com