



Lantheus To Present Piflufolastat F 18 Data at the Virtual Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2021 Annual Meeting

June 14, 2021

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jun. 14, 2021-- Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTX), 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, announced that data from the piflufolastat F 18 (formerly known as ¹⁸F-DCFPyL) CONDOR pivotal trial will be presented at the Virtual Society of Nuclear Medicine and Molecular Imaging (SNMMI) annual meeting.

Dr. Steven Rowe, Associate Professor of Radiology and Radiological Science at Johns Hopkins University, will deliver an oral presentation entitled: "A Phase 3 study of ¹⁸F-DCFPyL-PET/CT in Patients with Biochemically Recurrent Prostate Cancer (CONDOR): An Analysis of Disease Detection Rate and Positive Predictive Value (PPV) by Anatomic Region" on Tuesday, June 15, 2021. The presentation was also selected to be included in the Henry N. Wagner, Jr., MD Highlights Symposium plenary session.

In the CONDOR trial, piflufolastat F 18 detected and localized metastatic lesions with high positive predictive value (PPV) regardless of anatomic region in men with biochemically recurrent prostate cancer where standard imaging was uninformative. The median detection rates for prostate/prostate bed, lymph nodes and extra-pelvic region were: 20.2% (CI: 14.7-25.6%), 35.1% (CI: 28.6-41.6%) and 26.4% (CI: 20.4-32.4%), respectively. The median PPV (≥1 lesion confirmed) by anatomic region was: 79.5% (CI: 66.8-92.2%) for the prostate/prostate bed, 70.9% (CI: 58.9-82.9%) for pelvic lymph nodes and 67.4% (CI: 53.8-80.9%) for the extra-pelvic region.

Oral Presentation Details are as follows:

Title: A Phase 3 study of ¹⁸F-DCFPyL-PET/CT in Patients with Biochemically Recurrent Prostate Cancer (CONDOR): An Analysis of Disease Detection Rate and Positive Predictive Value (PPV) by Anatomic Region

Lead Author: Steven Rowe, Johns Hopkins University

Session Date and Time: June 15, 2021 2:00 - 3:00 PM ET

Session Title: Advances in PET Imaging for Cancer: Highlights of Clinical Diagnostics in Oncology

About PYLARIFY® (piflufolastat F 18) Injection

PYLARIFY® (piflufolastat F 18) injection (also known as ¹⁸F-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 radioisotope⁵ 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

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 2021, almost 250,000 new cases of prostate cancer will be diagnosed, and more than 30,000 men will die of the disease. Approximately 3.1 million men in the United States currently count themselves as prostate cancer survivors.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 $\leq 2\%$ 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 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; TechnelLite® (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 York, New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

¹Mena 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.

²Alipour 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.

³Werner 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.

⁴Petersen 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-

⁵Tan 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

⁶PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company

⁷American Cancer Society. Facts & Figures 2021. American Cancer Society. Atlanta, GA. 2021.

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