



Lantheus Announces Presentations Featuring PYLARIFY® (Piflufolastat F18), PYLARIFY AI™ and NM-01 (PD-L1 Imaging) at the 2022 Society for Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

May 26, 2022

NORTH BILLERICA, Mass., May 26, 2022 (GLOBE NEWSWIRE) -- 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 the following presentations at the upcoming 2022 Society for Nuclear Medicine and Molecular Imaging (SNMMI) Meeting, which will be held June 11-14, 2022 in Vancouver, BC, Canada.

Presentation details are as follows:

PYLARIFY® (Piflufolastat F18), PSMA-targeted PET imaging agent for prostate cancer

Oral Presentation:

Date & Time: June 14, 2022, 3:00 – 4:30 PM PT

Session Title: Urologic Malignancies

Title: The Impact of Concomitant Use of Androgen Deprivation Therapies (ADT) on the Efficacy of Piflufolastat F 18-PET/CT in Patients with Prostate Cancer: a Sub-group Analysis of OSPREY Cohort B

Presenter: Lawrence Saperstein, MD, Associate Professor of Clinical Radiology and Biomedical Imaging; Chief, Nuclear Medicine, Yale School of Medicine

Publication (Program ID): 2625

PYLARIFY AI™, FDA-cleared artificial intelligence platform developed to assist in standardized quantification of PSMA PET/CT scans

Oral Presentation:

Date & Time: June 12, 2022, 3:00 – 4:30 PM PT

Session Title: Oncology Basic/Translational Integrated Session

Title: Prospectively planned and Independent Validation of aPROMISE in a Phase III CONDOR Study for Rapid Lesion Detection and Standardized Quantitative Evaluation for ¹⁸F-DCFPyL (PSMA) Imaging in Prostate Cancer*

Presenter: Jeremie Calais, MD, MSc, Assistant Professor, Department of Molecular and Medical Pharmacology, Director, UCLA Theranostics Program, Ahmanson Translational Theranostics Division, University of California, Los Angeles

Publication (Program ID): 2496

*nominated for the Henry N. Wagner, Jr., MD "Image of the Year"

Poster Presentation:

Title: Quantitative Assessment of PSMA PET Response to Androgen Deprivation in Veterans with Treatment Naïve Castration Sensitive Prostate Cancer

Presenter: Nicholas G. Nickols, MD, PhD, Associate Professor in Radiation Oncology at UCLA

Publication (Program ID): 3070

Tc99m-NM-01, novel imaging agent currently under development for the assessment of PD-L1 expression in non-small cell lung cancer

Oral Presentation:

Date & Time: June 12, 2022, 12:30 – 2:00 PM PT

Session Title: Thoracic Malignancies: Breast and Lung

Title: SPECT/CT using ^{99m}Tc-labeled anti-programmed death-ligand 1 (PD-L1) single-domain antibody (NM-01) to predict response to immune checkpoint inhibition in non-small cell lung cancer: preliminary results from the PD-L1 Expression in Cancer (PECAN) study

Presenter: Daniel J. Hughes, Department of Cancer Imaging, School of Biomedical Engineering and Imaging, Sciences, King's College London, London, UK

Publication (Program ID): 2594

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; PYLARIFY AI[™], an artificial intelligence platform that assists in the evaluation of PSMA PET images; TechnoLit[®] (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.

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