Lantheus Announces PYLARIFY AI™ is Now Available

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

NORTH BILLERICA, Mass., Nov. 29, 2021 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus), 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 today that PYLARIFY AI™, its recently FDA-cleared medical device software, is now commercially available in the United States.

PYLARIFY AI employs a deep learning algorithm that has been trained and validated across more than 3,000 images to allow healthcare professionals and researchers to perform standardized quantitative assessment of PSMA PET/CT images in prostate cancer. Through rigorous analytical and clinical studies, PYLARIFY AI has demonstrated improved consistency, accuracy and efficiency in quantitative assessment of PSMA PET/CT.[1,2]

“PYLARIFY AI is the first and only FDA-cleared medical device software that offers a standardized platform for quantifying PSMA PET/CT images,” said Mary Anne Heino, President and Chief Executive Officer of Lantheus. “We believe that PYLARIFY AI could enhance the efficient integration of PSMA PET/CT into clinical practice and will be a vital tool to support the adoption of PYLARIFY.”

PYLARIFY AI can be deployed either as a secure web cloud application or within the secure firewall of the institution on a local server. Once deployed, the adaptive application can be integrated into an institution’s existing clinical workflow, delivering a unique combination of clinical utility and technical flexibility.

“PSMA PET imaging is revolutionizing the visualization of prostate cancer metastases and thus the staging of the disease. Additionally, used as a biomarker it can provide whole-body assessment of target expression before initiation of PSMA-targeted therapies,” said 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. “An application that provides a quantifiable and reproducible assessment of PSMA uptake and distribution in the body is critical to enabling widespread adoption of PSMA PET for staging, therapy response assessment and selection to or for PSMA-targeted therapy in patients with prostate cancer. The availability of PYLARIFY AI takes us one more step toward individualized, precision oncology.”

Syntermed, a leading provider of nuclear imaging software, has been appointed as the first distributor of PYLARIFY AI for the U.S.

For more information on PYLARIFY AI, please visit www.pylarify.com.

PYLARIFY AI

PYLARIFY AI™ Indications for Use
PYLARIFY AI is intended to be used by healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images. The system is intended to be used with images acquired using nuclear medicine (NM) imaging using PSMA PET/CT. The device provides general picture Archiving and Communications System (PACS) tools as well as a clinical application for oncology including marking of regions of interest and quantitative analysis.

PYLARIFY AI Warnings and Precautions
The user must ensure that the patient’s name, ID, and study date displayed in the patient section correspond to the patient case. The user must ensure the review of the image quality and quantification analysis results before signing the report. User must review the images and quantification results in the report to ensure that the information saved and exported is correct. The quantification analysis results provided by PYLARIFY AI are intended to be used as complementary information together with other patient information. The user shall not rely solely on the information provided by PYLARIFY AI for diagnostic or treatment decisions. Quantitative indexes (ITLV, and LI) are only appropriate for PSMA PET/CT images. User should not select hotspots for studies with images that do not fulfill the Quality Control requirements. In such cases, user can create and sign a report indicating that the review cannot be done due to image quality deficiencies.

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.[3]

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.[4-9]

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; 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 “believe,” “can,” “could,” “estimate,” “intend,” “may,” “target,” “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) the Company’s ability to successfully launch PYLARIFY AI as a commercial product; (ii) the market receptivity to PYLARIFY AI as a new digital application for quantitative assessment of PSMA PET/CT images in prostate cancer; (iii) the intellectual property protection of PYLARIFY AI; (iv) interruptions or performance problems associated with our digital application, including a service outage; (v) a network or data security incident that allows unauthorized access to our network or data or our customers’ data; and (vi) 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]Nickols N, Anand A, Johnsson K, et al. PYLARIFY AI: A Novel Automated-PROMISE platform to Standardize Evaluation of Tumor Burden in (18)F-DCFPyL (PSMA) images of Veterans with Prostate Cancer. J Nucl Med. 2021.

[2]Johnsson K, Brynolfsson J, Sahlstedt H, et al. Analytical performance of PYLARIFY AI: automated anatomic contextualization, detection, and quantification of [(18)F]DCFPyL (PSMA) imaging for standardized reporting. Eur J Nucl Med Mol Imaging. 2021.

[3]American Cancer Society. Facts & Figures 2021. American Cancer Society. Atlanta, GA. 2021.

[4]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

[5]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.

[6]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.

[7]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.

[8]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

[9]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