Lantheus' PYLARIFY AI™ Platform Demonstrates Higher Efficiency and Consistency While Maintaining Accuracy for Assessment of PSMA Imaging in Prostate Cancer

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Study Results Presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in Vancouver

NORTH BILLERICA, Mass., June 13, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("the Company") (NASDAQ: LNTH) is committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. Lantheus presented study results providing independent validation of PYLARIFY AI™, the Company's artificial intelligence (AI) platform developed to assist in standardized quantification of PSMA PET/CT scans. PYLARIFY AI is an FDA-cleared medical device software and is commercially available in the United States. The results were presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) annual meeting and demonstrated the higher efficiency and consistency of the PYLARIFY AI platform while maintaining the diagnostic accuracy of PSMA imaging in prostate cancer.

"This independent evaluation of PYLARIFY AI in the CONDOR study has demonstrated its ability for rapid lesion detection and reproducible quantitative assessment, while maintaining the diagnostic accuracy for PSMA PET imaging. Further validation is warranted to understand the utility of PYLARIFY AI in prognosis and treatment response with PSMA PET imaging," commented 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 (UCLA), who presented the study. "The widespread availability of PSMA PET imaging has revolutionized our ability to see metastases in the body and more accurately stage prostate cancer. Additionally, used as a whole-body imaging biomarker, it can provide guidance on therapeutic response before initiation of PSMA-targeted therapies. Whole-body quantitative parameters extracted from an AI platform can further enhance our knowledge in developing individualized, precision medicine for prostate cancer patients."

As part of the study, researchers set out to evaluate PYLARIFY AI against manual reads by blinded independent readers who analyzed the 208 patients with biochemical recurrent prostate cancer enrolled in the Phase 3 CONDOR study.[1] A total of 323 lesions were identified by Standard of Truth (SOT). In the sensitivity analysis against SOT, one reader demonstrated significant improvement of lesion detection with PYLARIFY AI compared to manual reads. In the other two readers, there was moderate improvement observed compared to manual reads.

Median reading times for reader one, two and three were 1.4 minutes, 1.2 minutes, and 1.4 minutes, respectively. The interquartile range of all reading times combined was 2.1 minutes. The reproducibility of per-lesion standard uptake value (SUV) measurements among the three readers was significantly higher with PYLARIFY AI (ICC 0.98 95% CI 0.96 to 0.99) than without (ICC 0.90 95% CI 0.88 to 0.91) $p<0.0001$.

"Lantheus is leading the way in harnessing the power of AI and machine learning technologies, together with our game-changing PSMA-targeted PET imaging agent PYLARIFY, to potentially transform the way that clinicians manage and treat prostate cancer," said Jean-Claude Provost, MD, Interim Chief Medical Officer, Lantheus. "Previous studies have shown how this technology can have utility as a complementary diagnostic tool, and with these results we continue to demonstrate PYLARIFY AI's reliability, its ability to improve workflow and how it can be applied to our mission to Find, Fight and Follow prostate cancer to improve patient outcomes."

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.[2]

About PYLARIFY AI™
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. An FDA-cleared medical device software, PYLARIFY AI is commercially available in the United States.

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 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.

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 60 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 to deliver better patient outcomes. Lantheus is headquartered in Massachusetts and has 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 "can," "continue," "developing," "enhances," "improve," "may," "potentially," "transform" 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 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]Morris MJ, Rowe SP, Gorin MA, et al. Diagnostic performance of 18F-DCFPYL-PET/CT in men with biochemically recurrent prostate cancer: results from the CONDOR phase III, multicenter study [published online ahead of print, February 23, 2021]. Clin Cancer Res. doi:10.1158/1078-0432.CCR-20-4573
[2]American Cancer Society. Facts & Figures 2022. American Cancer Society. Atlanta, GA. 2022.

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