Lantheus Presents Results from a PYLARIFY AI™ Study at the American Urological Association (AUA) Annual Meeting

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Retrospective analysis demonstrates reliability of PSMA scan indices as response-imaging biomarker to androgen therapy in prostate cancer

NORTH BILLERICA, Mass., May 16, 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, presented results from a retrospective analysis of quantitative PYLARIFY® (piflufolastat F18) PSMA scan indices as a response imaging-biomarker to androgen deprivation therapy in veterans with newly diagnosed metastatic prostate cancer.

Using PYLARIFY AI™ to locate PSMA-avid lesions and track changes over time, investigators were able to determine that the change in the automated PSMA scan indices for total lesion volume, and also separately in bone and lymph node were all significantly consistent with PSA response following therapy. The findings support further exploration of PYLARIFY AI as a tool to quantify treatment response not only in at the overall disease burden but also at the lesion level.

“PSMA imaging is quickly becoming an essential tool in our management of prostate cancer and PYLARIFY AI has the ability to reproducibly and rapidly quantify disease burden. I think it can be used to address many limitations of conventional imaging including in the assessments of response to therapy,” said Nicholas G. Nickols, MD, PhD, Associate Professor in Radiation Oncology at UCLA, who led the study and presented the findings. “Of particular interest, this study reveals a method for measuring treatment response in bone using PSMA PET imaging, which may ultimately lead to improving patient outcomes.”

The study included a retrospective analysis of 30 treatment naïve prostate cancer patients who had undergone androgen deprivation therapy with and without radiation. PSMA scans were performed prior to treatment and at least six months after initiation of treatment. The images of all patients were analyzed by PYLARIFY AI which was used to locate PSMA-avid lesions and track changes over time. The continuous change in quantitative PSMA indices was compared with the change in PSA. At treatment follow-up, patients had an average PSA decline of 97% (median PSA 0.02). Concurrently, the changes in total PSMA indices in lymph node (average decline 80%; IQR: 62% to 100%) and in bone (average decline: 51%; IQR: 14% to 87%) were found to be significantly associated with PSA decline (r=0.74; p=0.0001).

“As the use of PSMA PET imaging becomes more widespread and used to guide treatment decisions, capturing the data to produce quantifiable and reproducible insights across the treatment spectrum will be essential,” said Jean-Claude Provost, MD, Interim Chief Medical Officer, Lantheus. “This study demonstrates the power of PYLARIFY AI in augmenting the value of each scan and highlights the role PYLARIFY AI may play in assisting clinicians in determining the best path forward for treating individual patients.”

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 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 V1.0 is commercially available in the United States.

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

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