Lantheus Collaborates with The Prostate Cancer Clinical Trial Consortium (PCCTC) To Advance AI-Enabled Imaging Biomarkers in Prostate Cancer

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NORTH BILLERICA, Mass., Jan. 27, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus) announced that its subsidiary, EXINI Diagnostics AB (EXINI), has entered into a collaboration with the Prostate Cancer Clinical Trials Consortium (PCCTC) to advance artificial intelligence (AI)-enabled imaging biomarkers in prostate cancer.

The PCCTC is a premier multicenter clinical research organization specializing in cutting-edge prostate cancer research recognized for its culture of transparent project co-development between investigators, research sites and industry partners. The group's distinguished investigators work together on a single mission: to design, implement and complete hypothesis-driven trials in prostate cancer, translating scientific discoveries into improved standards of care.

Lantheus' prostate cancer AI platform, which includes FDA cleared medical devices for both PSMA PET/CT (aPROMISE) and bone scintigraphy (aBSI), will be used in specific clinical studies to assist in measuring imaging response in patients diagnosed with prostate cancer.

The intent of the strategic collaboration is to integrate Lantheus' AI platform into early phase PCCTC studies to advance the discovery, development and validation of novel AI-enabled biomarkers. Imaging biomarkers have the potential to play a significant role in both patient selection and response assessment of targeted therapies. Lantheus' AI platform has the potential to reduce the complexity and improve the utility of the rich data generated from the diverse imaging tools used in prostate cancer, including PSMA PET/CT, bone scintigraphy, MRI and CT.

"The PCCTC's mission is to make a significant impact on the lives of patients by keeping the pipeline primed with the most promising novel agents and validated biomarkers," said Jake Vinson, PCCTC CEO. "We are pleased to partner with Lantheus, a leader in the development of artificial intelligence software as a medical device for prostate cancer."

"Lantheus believes its artificial intelligence platform can expand the utility of imaging diagnostics for precision medicine in prostate cancer and evolve from single biomarker image analysis to an integrated clinical decision support system drawing on multiple biomarkers and clinical record data. This strategic partnership is a critical step forward to realize that vision," said Etienne Montagut, Chief Business Officer of Lantheus.

Prostate Cancer AI Platform
Lantheus' prostate cancer artificial intelligence platform includes FDA and CE cleared medical devices for both PSMA PET/CT and bone scintigraphy.

The aPROMISE product is a vendor-neutral stand-alone software as a medical device which quantifies PSMA PET/CT in prostate cancer. aPROMISE received FDA clearance in 2021 (K 211655). The product is enabled with a unique deep learning algorithm that leverages a novel database to assist in automated localization, segmentation, and quantification of potential lesions – a PSMA score/PSMA Scan Index.

The aBSI product is a vendor-neutral stand-alone software as a medical device that calculates the automated bone scan index in Technetium-99m bone scintigraphy of prostate cancer patients. aBSI received FDA clearance in 2019 (K191262). The product is enabled with a neural network that has been trained to automate the detection of hotspots and calculate the aBSI value.

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 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**.

About The Prostate Cancer Clinical Trials Consortium (PCCTC)
The Prostate Cancer Clinical Trials Consortium (PCCTC) was initiated in 2005 by the Prostate Cancer Foundation (PCF) and the U.S. Department of Defense (DOD) Prostate Cancer Research Program (PCRP) in response to critically unmet needs in prostate cancer clinical research identified by physician investigators and patient advocates. To fulfill their mission, the PCCTC developed a unique infrastructure which has fostered a culture of transparent project co-development between investigators, research sites and industry partners. Established as an independent entity in 2014, the PCCTC, LLC is now the nation's premier multicenter clinical research organization specializing in cutting-edge prostate cancer research. Through the collaborative nature and intellectual synergy of its leadership, the PCCTC remains poised to make a significant impact on the lives of patients by keeping the pipeline primed with the most promising novel agents and validated biomarkers. For more information, visit www.pcctc.org.

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 "advance," "development," "evolve," "expand," "objective," "potential," "vision," "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 PCCTC's ability to successfully integrate the Company's AI platform into early phase PCCTC studies; (ii) the intellectual property protection of the Company's AI platform; (iii) interruptions or performance problems associated with our AI platform, including a service outage; (iv) a network or data security incident that allows unauthorized access to our network or data or the PCCTC's investigators' data; and (v) 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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