



Lantheus Holdings to Showcase the Potential of PyL™ Imaging Agent at the Virtual Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2020 Annual Meeting

Jul 1, 2020

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jul. 1, 2020-- Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTN), the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products, today announced that 17 abstracts highlighting PyL™ (18F-DCFPyL) have been selected for presentation at the virtual Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2020 Annual Meeting taking place July 11-14, 2020. PyL is the PSMA-targeted small molecule positron emission tomography (PET) imaging investigational agent designed to visualize prostate cancer, which the Company recently purchased as part of the oncology business of Progenics.

The abstracts to be presented at the meeting will feature data on PyL from two presentations based on Company-sponsored studies, including the positive results from the Phase 3 CONDOR trial evaluating the diagnostic performance and clinical impact of PyL in patients with biochemical recurrence of prostate cancer. A third abstract focuses on the digital solution the Company is developing in parallel with PyL to potentially support prostate cancer staging using an automated miPSMA Index of the PET/CT PyL-PSMA images.

"Physicians and patients continue to experience an unmet need for diagnostic imaging that could assist in staging high risk prostate cancer and reliably detect recurrent or metastatic disease. The unmet need is particularly important among patients with low PSA values," said Istvan Molnar, M.D., the Company's Chief Medical Officer. "We believe that the demonstrated strong diagnostic performance of our PSMA-targeted PET imaging investigational agent, PyL, could provide clinicians with actionable information. In addition, the use of the widely available isotope fluorine-18 may result in broad patient accessibility. Data to be presented at SNMMI this year further highlights PyL's clinical potential, including the positive Phase 3 results of the CONDOR study, which achieved its primary endpoint with a correct localization rate of 84.8% to 87.0% among the three blinded independent readers. We remain on track to submit a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for PyL in the third quarter of 2020."

SNMMI presentations will be made available on July 11, 2020 and can be found in the virtual [Science Pavilion](#).

Details for the SNMMI 2020 presentations based on Company-sponsored studies and Company-led digital solution development are as follows:

Title: Diagnostic Performance of PSMA-Targeted ¹⁸F-DCFPyL PET/CT in Men with Biochemically Recurrent Prostate Cancer: Results from the Phase 3, Multicenter CONDOR Study

Lead Author: Steven Rowe, Johns Hopkins University

Title: miPSMA Index: Comprehensive and Automated Quantification of ¹⁸F-DCFPyL (PyL-PSMA) PET/CT for Prostate Cancer Staging

Lead Author: Kerstin Johnsson, Progenics Pharmaceuticals

Title: Measuring bias in quantitative PET biomarkers in-vivo

Lead Author: Martin Lodge, Johns Hopkins University

About PyL™ for PET Imaging of Prostate Cancer

PyL (also known as ¹⁸F-DCFPyL) is a fluorinated PSMA-targeted positron emission tomography (PET) imaging agent that enables visualization of both bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in nine men will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that each year approximately 174,650 new cases of prostate cancer will be diagnosed and about 31,620 men will die of the disease. Approximately 2.9 million men in the U.S. currently count themselves among prostate cancer survivors.

About Lantheus Holdings, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; TechnoLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; RELISTOR® for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc.; and AZEDRA® for the treatment of certain rare neurological cancers. The Company is headquartered in North Billerica, Massachusetts with offices in New York, New Jersey, Puerto Rico, Canada and Sweden. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “should,” “plan,” “could,” “target,” “contemplate,” “estimate,” “predict,” “potential,” “opportunity,” “creates” and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, are forward-looking statements. Important factors that could cause actual results to differ materially from Lantheus’ plans, estimates or expectations could include, but are not limited to: (i) the timing of the filing of the Company’s PyL NDA with the FDA; (ii) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and other regulatory authorities; (iii) the Company’s ability to successfully launch PyL as a commercial product; (iv) the market receptivity to PyL as a new diagnostic agent; (v) the safety and efficacy of PyL; and (vi) the intellectual property protection of PyL. Additional factors that may affect the future results of Lantheus are set forth in Lantheus’ filings with the SEC, including Lantheus’ most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at www.sec.gov. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that Lantheus file from time to time with the SEC. The forward-looking statements in this document speak only as of the date of these materials. Except as required by law, Lantheus assumes no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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Investors:

Mark Kinarney
Senior Director, Investor Relations
978-671-8842

Melissa Downs
Associate Director, Communications
646-975-2533

Source: Lantheus Holdings, Inc.