# Lantheus Announces Publication of PyL™ (18F-DCFPyL) Results from Pivotal Studies

Mar 1, 2021

***OSPREY Phase 2/3 Results Published in the Journal of Urology***

***CONDOR Phase 3 Results Published in Clinical Cancer Research***

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Mar. 1, 2021-- Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus), an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find, Fight and Follow serious medical conditions, today announced the publication of the results of both pivotal studies for PyL™, an investigational PET imaging agent that targets prostate-specific membrane antigen (PSMA). The OSPREY Phase 2/3 trial results have been published online in the *Journal of Urology* and the CONDOR Phase 3 trial results have been published in the online version of *Clinical Cancer Research*.

"The limitations of conventional imaging modalities for prostate cancer create a need for targeted imaging in the initial assessment of high-risk patients as well as in men with early biochemically relapsed disease," said Michael J. Morris, M.D., Prostate Cancer Section Head, Genitourinary Medical Oncology Service, Division of Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center, and lead author of the CONDOR manuscript and senior author on the OSPREY manuscript. "The OSPREY trial data highlighted the high positive predictive value, negative predictive value and specificity of PyL in staging high-risk patients. The CONDOR trial demonstrates its high positive predictive value to accurately locate and identify recurrent cancer early and non-invasively. Assuming FDA approval, physicians will be able to use this clinically meaningful information to identify disease, guide treatment plans, and improve disease management."

Mary Anne Heino, President and Chief Executive Officer of Lantheus added, "We believe these data demonstrate PyL's clinical benefit and are honored to have our studies published in such well-respected peer-reviewed journals. The results of the OSPREY and CONDOR trials are part of our NDA that is currently under priority review at the FDA for marketing authorization in the United States. We believe PyL has the potential to play an important role in transforming the management of men with high-risk, recurrent or metastatic prostate cancer."

Kenneth J. Pienta, M.D., Director of Research at the James Buchanan Brady Urological Institute and Professor of Urology at Johns Hopkins University School of Medicine, was the lead author of the OSPREY manuscript. The OSPREY publication in the Journal of Urology may be found online here.

Michael J. Morris, M.D., Prostate Cancer Section Head of the Genitourinary Medical Oncology Service and Division of Solid Tumor Oncology at Memorial Sloan Kettering Cancer Center. Was the lead author of the CONDOR manuscript. The CONDOR publication in Clinical Cancer Research may be found online here.

**OSPREY Phase 2/3 Trial**

The OSPREY trial was designed to assess the diagnostic performance of PyL to detect prostate cancer in pelvic lymph nodes in subjects with high-risk prostate cancer (Cohort A) and confirm distant metastases in subjects with metastatic or recurrent prostate cancer (Cohort B). The primary endpoints for the trial were sensitivity and specificity of PyL PET/CT imaging to detect metastatic prostate cancer within the pelvic lymph nodes relative to histopathology in Cohort A. A key secondary endpoint of the trial was the sensitivity of PyL PET/CT imaging to detect prostate cancer within sites of metastasis or local recurrence relative to histopathology in Cohort B.

In the trial, the diagnostic performance of PyL in detecting disease in pelvic lymph nodes (Cohort A) was compared with histopathology. PyL showed specificity of 96-99%, sensitivity of 31-42%, and PPV of 78-91% meeting the specificity but not the pre-established sensitivity co-primary endpoint. In the metastatic or recurrent prostate cancer setting (Cohort B), PyL exhibited sensitivity of 93-99% and PPV of 81-88% in detecting metastatic lesions. Overall, PyL demonstrated high diagnostic performance in reliably detecting nodal and distant metastatic prostate cancer.

Safety results showed PyL was well tolerated. The most frequent adverse events reported were dysgeusia (2.6%), headache (1.8%), and fatigue (1.3%).

**CONDOR Phase 3 Trial**

The CONDOR trial was designed to assess the diagnostic performance and clinical utility of PyL in men with biochemically recurrent prostate cancer and uninformative standard imaging. The primary endpoint in the trial was the Correct Localization Rate (CLR) of PyL. CLR is based on positive predictive value, defined as the percentage of patients with a one-to-one correspondence between localization of at least one lesion identified on PyL PET/CT and a composite truth standard. The composite truth is

comprised of, in descending priority, histopathology, subsequent correlative imaging findings, or PSA response following radiation therapy. The key secondary endpoint in the trial was the percent of subjects with a change in intended prostate cancer treatment due to PyL imaging results.

The CONDOR trial achieved its primary endpoint, with a CLR of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). In the key secondary endpoint, 63.9% of patients had a change in intended prostate cancer treatment following review of PyL imaging results. The most frequent changes in intended prostate cancer treatment plans included changing salvage local therapy to systemic therapy, observation to initiating therapy, noncurative systemic therapy to salvage curative local therapy and planned treatment to observation.

Safety results showed PyL was well tolerated. The most frequent adverse event reported was headache, which was reported in four patients (1.9% of the trial population). There was one serious adverse event of hypersensitivity reported as related to the study drug.

**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, 248,530 new cases of prostate cancer will be diagnosed, and 34,130 men will die of the disease. Approximately 3.1 million men in the United States currently count themselves as prostate cancer survivors.[1]

**About PyL**
PyL (also known as 18F-DCFPyL) is an investigational fluorinated PSMA-targeted PET imaging agent that enables visualization of localized prostate cancer both localized as well as metastatic to lymph nodes, bone and soft tissue to detect and localize recurrent and/or metastatic prostate cancer. On September 29, 2020, Lantheus submitted a new drug application (NDA) for PyL which was accepted and granted priority review and assigned a Prescription Drug User Fee Act (PDUFA) action date of May 28, 2021.

**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 of 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; 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 York, 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 “expect,” “intend,” “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) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and other regulatory authorities for PyL; (ii) the Company’s ability to successfully launch PyL as a commercial product; (iii) the market receptivity to PyL as a new diagnostic agent; (iv) the safety and efficacy of PyL; (v) the intellectual property protection of PyL; and (vi) the risk 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).

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

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