Lantheus Holdings Announces Acceptance and Priority Review of New Drug Application for PyLTM (18F-DCFPyL), a PSMA-Targeted Prostate Cancer PET Imaging Agent

Dec 9, 2020

PDUFA action date of May 28, 2021 assigned by U.S. Food and Drug Administration

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Dec. 9, 2020-- Lantheus Holdings, Inc. (NASDAQ: LNTH) (the Company), 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 the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for PyL™ (18F-DCFPyL), a prostate specific membrane antigen (PSMA)-targeted positron emission tomography (PET) imaging agent for prostate cancer.

The FDA granted Priority Review for the PyL NDA and assigned a Prescription Drug User Fee Act (PDUFA) action date of May 28, 2021. The FDA has also indicated in the NDA filing acceptance notification that it is not currently planning to hold an advisory committee meeting to discuss the application.

“We are pleased that the FDA has accepted our PyL NDA for review and granted our application Priority Review, which is a significant milestone for Lantheus. We believe that there is a significant unmet need for reliable, targeted imaging in prostate cancer, particularly in the high risk and biochemically recurrent populations,” said Istvan Molnar, MD, Chief Medical Officer of Lantheus. “We look forward to working with the FDA during the NDA review process with the goal of bringing PyL to patients and physicians who need it.”

The PyL NDA is supported by data from two Company-sponsored pivotal studies (OSPREY and CONDOR) designed to establish the safety and diagnostic performance of PyL imaging across the prostate cancer disease continuum. Results from OSPREY Cohort A demonstrated improvement in specificity and positive predictive value (PPV) of PyL PET imaging over conventional imaging in men with high risk prostate cancer. OSPREY Cohort B and CONDOR studied men with prostate cancer in various disease states, including biochemical recurrent, hormone sensitive, non-metastatic castrate resistant, and metastatic castrate resistant. OSPREY Cohort B demonstrated the sensitivity of PyL PET imaging in detecting metastatic lesions, while CONDOR, in patients with biochemical recurrent prostate cancer and non-informative baseline findings, demonstrated PyL’s high correct localization rate and detection rate, including in patients with low PSA values. In the CONDOR study, 63.9% of patients had a change in intended disease management plans due to the PyL PET imaging results. We believe the results from these two studies, taken as a whole, demonstrate the ability of PyL to reliably detect and localize disease and could enable more appropriate patient management.

PyL has been administered in approximately 3,500 subjects globally, including the two Company-sponsored pivotal studies, multiple investigator sponsored studies, as well as clinical use reported in the literature. Across these studies, PyL has shown an attractive safety profile.

About PyL™ for PET Imaging of Prostate Cancer

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

About OSPREY

The Phase 2/3 OSPREY trial assessed the diagnostic performance of PyL to detect prostate cancer in pelvic lymph nodes in subjects with high risk, locally advanced prostate cancer (Cohort A) and distant metastases in subjects with metastatic or recurrent prostate cancer (Cohort B). In the trial, the diagnostic performance of PyL in detecting disease in pelvic lymph nodes (Cohort A) showed specificity of 96-99%, sensitivity of 31-42%, and PPV of 78-91% although the trial did not meet one of its the primary endpoints. 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.

About CONDOR

The Phase 3 CONDOR trial evaluated the diagnostic performance and clinical impact of PyL in men with biochemical recurrence of prostate cancer and uninformative baseline imaging based on conventional modalities. The CONDOR trial achieved its primary

endpoint, with a correct localization rate (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%). CLR is based on positive predictive value, defined as the percentage of subjects with a one-to-one correspondence between localization of at least one lesion identified on PyL PET/CT and a composite truth standard comprised of histopathology, conventional imaging and/or changes in PSA levels following radiation therapy. 63.9% of subjects in the CONDOR trial had a change in intended disease management plans due to PyL imaging results, a key secondary endpoint of the trial. The changes to treatment management plans due to the PyL results included salvage local therapy to systemic therapy, observation to initiating therapy, noncurative systemic therapy to salvage local therapy, and planned treatment to observation.

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 192,000 new cases of prostate cancer will be diagnosed, and 33,000 men will die of the disease. Approximately 3.2 million men in the United States currently count themselves among prostate cancer survivors.[1]

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; 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, Puerto Rico, 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 “anticipate,” “believe,” “confident,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “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) 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]National Cancer Institute. SEER Cancer Stat Facts: Prostate Cancer. Accessed at https://seer.cancer.gov/statfacts/html/prost.html on March 15, 2019.

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