PyL™ (18F-DCFPyL), Lantheus' PSMA-Targeted Prostate Cancer Imaging Agent, to be Used in POINT Biopharma's PSMA-Targeted Radioligand Therapeutic Phase 3 Trial in Patients with Metastatic Castration Resistant Prostate Cancer

Dec 9, 2020

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Dec. 9, 2020-- Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus), the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products, today announced it has entered into a strategic collaboration with POINT Biopharma, Inc. (POINT) to use Lantheus' investigational prostate-specific membrane antigen (PSMA)-targeted positron emission tomography (PET) imaging agent, PyL, to determine PSMA-avidity during patient selection in POINT's Phase 3 clinical trial to treat metastatic castration resistant prostate cancer (mCRPC). The collaboration directly aligns with an important Lantheus strategy to advance cancer precision medicine by enabling partners to use PyL in prostate cancer therapeutic trials.

As part of the agreement with POINT, Lantheus' subsidiary, Progenics Pharmaceuticals, Inc., will supply PyL at a predetermined supply price.

"While there have been great advances in the treatment of prostate cancer, there remains an important unmet medical need for therapies that can more specifically target metastatic prostate cancer," said Mary Anne Heino, President and Chief Executive Officer of Lantheus. "The inclusion of PyL in POINT's Phase 3 trial reinforces our belief in the potential utility of PyL, not just in assessing metastatic disease, but also in selecting the most appropriate patients for PSMA-targeted therapy."

POINT will conduct a Phase 3, multicenter, open-label, randomized clinical trial to evaluate the efficacy and safety of their novel PSMA-targeted radioligand, ^{177}Lu-PNT2002, in patients with mCRPC. PyL will be used to select patients with PSMA-avid tumors for treatment with ^{177}Lu-PNT2002, and in a subset of patients also be used to evaluate progression.

"The combination of diagnostic imaging and radioligand therapy is a validated approach and an important development in cancer treatment," said Joe McCann, Chief Executive Officer of POINT. "POINT is very excited to be enrolling our study using PyL. We believe this promising biomarker will help identify the patients with prostate cancer who will best respond to PNT 2002, our next generation radioligand therapy."

About PSMA

PSMA is a protein that has been found to be amplified on the surface of greater than 95% of prostate cancer cells and is a validated target for the detection of primary and metastatic prostate cancer.[1]

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. On September 29, 2020, Lantheus filed with the U.S. Food and Drug Administration a New Drug Application for PyL.

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 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 U.S. currently count themselves among prostate cancer survivors.[3]

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.

About POINT Biopharma, Inc.

POINT Biopharma is a globally focused radiopharmaceutical company building a platform for the clinical development and commercialization of radioligands that fight cancer. POINT is combining a portfolio of best in class radiopharmaceutical assets, a seasoned management team, strategic partnerships in radio-isotope supply, manufacturing technology and novel direct to patient targeting to revolutionize theragnostic drug development and radioligand commercialization. For more information about radioligands, visit https://www.radioligands.org. For more information about POINT, visit https://www.pointbiopharma.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," "estimate," "expect," "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) regulatory risks related to PyL; (ii) expectations for POINT's clinical trial and future clinical trials, the timing and potential outcomes of clinical studies and filings and other interactions with regulatory authorities; (iii) the impact of legislative, regulatory, competitive and technological changes; (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]Wright, et al. Expression of Prostate-Specific Membrane Antigen in Normal, Benign, and Malignant Prostate Tissue. Urol Oncol 1995;1:18028.

[2]S Hammer, et. al. Preclinical Efficacy of PSMA-Targeted Thorium-227 Conjugate (PSMA-TTC), a Targeted Alpha Therapy for Prostate Cancer. Clin Cancer Res 2020; Published Online First December 12, 2019.

[3]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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Source: Lantheus Holdings, Inc.