EXINI Diagnostics AB, a Lantheus Company, Receives CE Mark Clearance for aPROMISE in Europe

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NORTH BILLERICA, Mass.--(BUSINESS WIRE)--May 3, 2021-- EXINI Diagnostics AB, a subsidiary of Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus), an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics and artificial intelligence (AI) solutions to Find, Fight and Follow serious medical conditions, announced today that it has received CE Mark clearance for aPROMISE in Europe.

aPROMISE is artificial intelligence-based, deep learning-enabled, medical device software that allows healthcare professionals and researchers to perform quantitative assessment of prostate-specific membrane antigen (PSMA) PET/CT in oncology. aPROMISE includes a solution for automated body segmentation and marking, quantifying and reporting suspicious lesions in their anatomical context.[1,2] The AI tool provides enhanced consistency in quantitative analysis and is intended to increase efficiency, accuracy and reproducibility of PSMA PET/CT image assessments.

In a prospectively planned independent analysis of the PyL OSPREY trial, aPROMISE demonstrated a high reproducibility with an intraclass correlation coefficient (ICC) of 0.99 (95%CI 0.99 - 0.99). In metastatic prostate cancer patients, the sensitivity of aPROMISE in a pre-selection of lesions was 92% for regional lymph nodes, 91% for distant lymph nodes, and 87% for bone.

“The Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE) criteria has proposed a uniform language for objective reporting to assist physicians in assessing a patient’s tumor burden and also provides clinically meaningful information to physicians for developing therapeutic plans,” said Matthias Eiber, Department of Nuclear Medicine, Klinikum Rechts der Isar, Technical University of Munich, Munich, Germany. “With the introduction of automation to the PROMISE criteria, the software is able to facilitate adherence to standardized reporting in clinical practice by reducing reporting time and limitations of manual assessment.”

“The aPROMISE CE Mark clearance is an exciting milestone for Lantheus on the path to possible U.S. approval later this year,” said Etienne Montagut, Sr. Vice President, Corporate Development. “We believe aPROMISE is a unique offering that could complement and strengthen our PSMA assets portfolio by improving their value and ease of use while assisting treating clinicians in their patient management decisions.”

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.[3]

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.

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%).

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, please 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 “believe,” “could,” “expect,” “intend,” “possible,” “propose,” “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 or aPROMISE; (ii) the Company’s ability to successfully launch aPROMISE as a commercial product; (iii) the market receptivity to using artificial intelligence-based, deep learning-enabled, medical device software; (iv) the intellectual property protection of aPROMISE; and (v) 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] Deep Learning-Enabled Comprehensive Detection and Quantification of 18FDCFPyL (PyL-PSMA) PET/CT. Brynolfsson J, Johnsson K, Sahlstedt H, Richter J, et al, OP-548, 1006: Cutting Edge Science Track – TROP Session: AI -Radiomics and Modelling, EANM 2020.

[2] miPSMA Index: Comprehensive and Automated Quantification of 18F-DCFPyL (PyL-PSMA) PET/CT for Prostate Cancer Staging. Johnsson K, Sahlstedt H, Brynolfsson J, et al. J Nucl Med. 2020;61(1):1435

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

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