Lantheus to Present New Data at the ASNC Annual Scientific Session on the Novel PET Cardiac Imaging Agent Flurpiridaz F 18 in Patients with Suspected Heart Disease Undergoing Exercise Stress Testing

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Findings Show Superiority of Flurpiridaz F 18 PET MPI Compared to SPECT MPI for the Assessment of Coronary Artery Disease During Exercise Stress Testing

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Sep. 22, 2016-- Lantheus Holdings, Inc. (NASDAQ: LNTH), the parent company of Lantheus Medical Imaging, Inc. ("LMI"), a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents, today announced that new data from a sub-analysis of its first Phase 3 study of flurpiridaz F 18 for myocardial perfusion imaging (MPI) in patients undergoing exercise stress testing will be presented at the 21st Annual Scientific Session of the American Society of Nuclear Cardiology (ASNC) in Boca Raton, Florida. The findings show the superiority of flurpiridaz F 18, an investigational positron emission tomography (PET) agent for MPI, compared to MPI with single photon emission computed tomography (SPECT) for the assessment of coronary artery disease (CAD) during exercise stress testing.

The oral presentation entitled, "Exercise Stress Testing with Flurpiridaz F 18 PET and Tc99m SPECT Myocardial Perfusion Imaging for the Assessment of CAD: A Subset Analysis of the Flurpiridaz F 18 301 Phase 3 Study," will be presented by Rob Beanlands, M.D. of University of Ottawa Heart Institute on Saturday, September 24, 2016 at 10:45 a.m. ET in the Featured Oral Abstracts session of the meeting.

"Due to short half-life limitations of currently available tracers ($^{13}NH_3$ and ^{82}Rb), PET myocardial perfusion imaging is commonly used in conjunction with pharmacologic stress testing," said Dr. Beanlands, the lead author of the presentation. "The ability to perform PET imaging with exercise stress would allow us to gather important additional clinical information and also to use the same camera for both stress modalities. The results of this study provide evidence of the particular utility and future potential of flurpiridaz F 18 PET imaging for the diagnosis of coronary artery disease."

Based on a blinded read of PET and SPECT data, flurpiridaz F 18 PET imaging demonstrated a statistically greater sensitivity (67.0%) versus SPECT (54.9%) ($p<0.016$) but lower specificity (73.8%) versus SPECT (85.4%) (non-significant for non-inferiority testing). Improved diagnostic performance of flurpiridaz F 18 PET imaging versus SPECT was also observed by ROC analysis ($p<0.05$). A significantly higher percentage of images were rated as either excellent or good quality with flurpiridaz F 18 PET imaging, compared to SPECT for rest images ($p<0.001$). No drug-related serious adverse events were observed.

The data are from a multicenter, international (United States, Canada, and Finland) Phase 3 study of flurpiridaz F 18 PET imaging. The study enrolled approximately 800 patients with known or suspected CAD who were scheduled for coronary angiography and conventional SPECT. Of these patients, 221 patients with known or suspected CAD underwent exercise stress flurpiridaz F 18 PET and SPECT imaging and coronary angiography.

"The Phase 3 data sub-analysis presented at ASNC demonstrates the ability to conduct flurpiridaz F 18 PET imaging for coronary artery disease detection in association with exercise stress testing," said Cesare Orlandi, M.D., Chief Medical Officer of Lantheus Medical Imaging. "Flurpiridaz F 18 PET imaging also shows superiority over SPECT in this subpopulation not assessable with current standard PET imaging modalities. We believe improved diagnostic accuracy, coupled with reduced radiation exposure and potential for quantification of coronary flow reserve provide great promise for flurpiridaz F 18 to become the diagnostic imaging agent of choice for evaluating coronary artery disease."

Lantheus is poised to commence the second of two Phase 3 trials for flurpiridaz F 18 PET imaging with a revised protocol in place under an FDA-approved Special Protocol Assessment and is in active negotiations with potential strategic partners to assist with the further development, manufacture and commercialization of this promising agent.

About the Flurpiridaz F 18 First Phase 3 Study

The first flurpiridaz F 18 Phase 3 study was designed to assess the diagnostic efficacy of flurpiridaz F 18 PET imaging versus SPECT with Tc99m-labeled agents for CAD detection in the same patients. Patients with known or suspected CAD who were either scheduled for or had completed invasive coronary angiography (without intervention) were included in the study. Each patient was studied using both one-day rest/stress flurpiridaz F 18 PET imaging and Tc99m-labeled SPECT imaging (one-day rest/stress or two-day protocol). Images were interpreted by three expert readers blinded to all clinical information. Quantitative coronary angiography (QCA) was used as the truth standard, with patients considered CAD positive with a stenosis ≥ 50% in at least one major vessel by QCA. Flurpiridaz F 18 PET imaging substantially outperformed SPECT, in sensitivity, one of the study's primary endpoints, but did not meet the study's other primary endpoint, non-inferiority for specificity, implying a substantial and unexpected under-diagnosis of CAD with SPECT in the trial. Unlike flurpiridaz F 18 PET imaging, SPECT results were skewed with low sensitivity and high specificity when compared to the truth standard. In secondary endpoints, flurpiridaz F 18 PET imaging outperformed SPECT in image quality and diagnostic certainty with less than half of the radiation exposure for patients. Subsequent to the initial read of the data, LMI performed a re-read which confirmed the initial results as well as showed improved performance of flurpiridaz F 18 PET imaging as compared to SPECT in women and subjects with high body mass index. Based on the results of the first Phase 3 study, the Company redesigned the protocol for its second Phase 3 study, including different primary endpoints – namely, the performance of flurpiridaz F 18 on its own merit versus coronary angiography as the truth standard – and the Company has received a Special Protocol Assessment from the FDA in connection with its second study.

About Flurpiridaz F 18 and Coronary Artery Disease

Flurpiridaz F 18, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1)[1], was designed to be a novel PET imaging agent that may better evaluate patients with known or suspected CAD, which is the most common form of heart disease[2], affecting an estimated 15.5 million Americans 20 years of age or older[3]. CAD is the leading cause of death in the United States for both men and women[2]. Each year more than 400,000 Americans die from CAD[2]. In the first phase 3 study, flurpiridaz F 18 demonstrated improved CAD detection and reduced radiation exposure over

standard SPECT. In subgroup analyses, the risk-benefit profile of flurpiridaz F 18 PET imaging appeared to be favorable in women, obese patients and patients with multivessel disease. It is important to note that, with a 110 minute half-life, flurpiridaz F 18 can be used in conjunction with treadmill exercise, which is not feasible with other currently used PET tracers for MPI.

About PET and MPI

PET imaging or a PET scan is a type of nuclear medicine imaging procedure[4] that provides information about the function and metabolism of the body's organs, unlike computed tomography (CT) or magnetic resonance imaging (MRI), which primarily show anatomy and structure [5]. MPI is a non-invasive test that utilizes a small amount of radioactive material (radiopharmaceutical) injected into the body to depict the distribution of blood flow to the heart. MPI is used to identify areas of reduced blood flow to the heart muscle. The test is typically conducted under both rest and stress conditions, after which physicians examine and compare the two scans and predict whether the patient has significant coronary artery disease[6]. Although SPECT is most commonly used for MPI[7], PET imaging has gained considerable support and use in the field of cardiovascular imaging, as it offers many advantages to SPECT, including higher spatial and contrast resolution, resulting in higher image quality and improved diagnostic accuracy, accurate attenuation correction and risk stratification[8].

About Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. LMI provides a broad portfolio of products, which are primarily used for the diagnosis of cardiovascular diseases. LMI's key products include the echocardiography contrast 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; and Xenon (Xenon Xe 133 Gas), an inhaled radiopharmaceutical imaging agent used to evaluate pulmonary function and for imaging the lungs. LMI is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

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This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to risks and uncertainties that may be described from time to time in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus 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.

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