Lantheus Medical Imaging Presents Phase 2 Study Results of PET Myocardial Perfusion

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Data Show PET Imaging with Flurpiridaz F 18 Provides Superior Image Quality, Diagnostic Certainty and Diagnostic Performance Compared with SPECT Imaging in Detection of Coronary Artery Disease

N. BILLERICA, Mass. (May 17, 2011) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced data from a Phase 2 clinical trial that demonstrated Positron Emission Tomography (PET) myocardial perfusion imaging with flurpiridaz F 18 provided superior image quality, diagnostic certainty and diagnostic performance for detecting coronary artery disease (CAD) compared to single photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), the current standard for the non-invasive detection of CAD. The data also demonstrated a positive safety profile for PET imaging with flurpiridaz F 18. The data were featured today in a late-breaking presentation by Jamshid Maddahi, M.D., F.A.C.C., Professor of Molecular and Medical Pharmacology (Nuclear Medicine) and Medicine (Cardiology) at the David Geffen School of Medicine at UCLA, and Lead Principal Investigator of the study, at ICNC10 - Nuclear Cardiology and Cardiac CT Conference in Amsterdam.

"Results from this Phase 2 trial show that PET myocardial perfusion imaging with flurpiridaz F 18 demonstrate a strong safety profile and is superior to SPECT imaging with respect to the quality of rest and stress images, certainty of image interpretation, and diagnostic performance as measured by standard ROC analysis for detecting CAD," said Dr. Maddahi. "Overall, this enhanced diagnostic performance may lead to more accurate testing and more appropriate patient management decisions in comparison to other non-invasive diagnostic modalities and, as such, we see great value in proceeding to Phase 3 clinical trials."

In the Phase 2 trial, 143 patients from 21 centers underwent rest and stress PET and SPECT myocardial perfusion imaging and were evaluated for safety. Of these patients, 86 underwent coronary angiography and formed the population for evaluating diagnostic performance. PET myocardial perfusion imaging was performed with flurpiridaz F 18 at rest and at stress utilizing pharmacological coronary vasodilation or treadmill exercise. It is important to note that flurpiridaz F 18 can be used in conjunction with treadmill exercise, which is not feasible with more commonly used alternative PET tracers for myocardial perfusion imaging.

Results showed that a significantly higher percentage of images were rated as either excellent or good quality with PET imaging, compared to SPECT imaging for stress images (98.8% vs. 84.9%, $p<0.01$) and rest images (95.3% vs. 69.8%, $p<0.01$). Diagnostic certainty of interpretation (the percentage of cases with definitely abnormal or definitely normal interpretation) was significantly higher for PET compared to SPECT (90.7% vs. 75.6%, $P<0.01$). The area under the ROC curve for CAD diagnosis was significantly higher for PET than SPECT (0.82±0.05 vs. 0.70±0.05, $p<0.05$). Sensitivity with PET imaging was significantly higher than SPECT (78.8% vs. 61.5%, $p=0.02$). Although a trend toward higher specificity was noted, due to the limited number of patients the study was not powered to conclusively demonstrate this advantage. No drug-related serious adverse events were observed.

"The Phase 2 trial of PET imaging with flurpiridaz F 18 met all study objectives and we are very pleased with the study findings, which show a trend toward improved diagnostic performance compared to SPECT MPI for the detection of CAD," said Dana S. Washburn, M.D., Vice President, Clinical Development and Medical Affairs at Lantheus Medical Imaging. "PET imaging has gained considerable support in the field of cardiovascular imaging, as it offers many advantages to SPECT imaging. Flurpiridaz F 18 shows great promise as a novel PET myocardial perfusion imaging tool and we look forward to initiating our Phase 3 clinical development program of flurpiridaz F 18 in the second quarter of this year."

In March 2011, Lantheus received Special Protocol Assessment approval from the FDA for the Phase 3 trial of flurpiridaz F 18. The Phase 3 clinical development program will include two open-label, multicenter trials to assess the diagnostic efficacy (both sensitivity and specificity) of flurpiridaz F 18 PET MPI, compared with SPECT myocardial perfusion imaging in the detection of significant coronary artery disease. The trials will enroll a total of approximately 1,350 patients at approximately 100 sites globally. Coronary angiography will be the truth standard for all patients. The clinical development program includes hypotheses for superiority for sensitivity and non-inferiority for specificity with an adequate sample size to demonstrate superior specificity if present. An interim analysis will take place upon 50 percent enrollment of the first trial.

About Flurpiridaz F 18 Injection and Coronary Artery Disease

Flurpiridaz F 18 injection, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1)[1], was designed to be a novel myocardial perfusion PET imaging agent for the diagnosis of coronary artery disease (CAD). PET imaging with flurpiridaz F 18 has the potential to be a new clinical tool for the evaluation of myocardial perfusion that may better evaluate patients with known or suspected CAD in comparison to other non-invasive diagnostic modalities. CAD is the most common form of heart disease, affecting approximately 16.8 million people in the United States[2]. CAD is the leading cause of death in the United States for both men and women[3]. Each year more than half a million Americans die from CAD3.

About PET and MPI

Positron Emission Tomography, also called 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]. Myocardial perfusion imaging (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 (perfusion) 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 single-photon emission computer tomography (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, which results in higher image quality and improved diagnostic accuracy, accurate attenuation correction and risk stratification[8].

About Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for more than 50 years, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The company's proven success in discovering, developing and marketing innovative medical imaging agents provides a strong platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. Lantheus imaging products include the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, ABLAVAR® (gadofosveset trisodium), a first-in-class magnetic resonance agent indicated for the evaluation of aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease, TechneLite® (Technetium Tc99m Generator), Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride Tl 201 Injection). Lantheus has more than 650 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. 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. Such forward-looking statements are subject to risks and uncertainties, including but not limited to, statements regarding the expected timing of the initiation of clinical trials, the expected number of patient enrollment and other factors 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. 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.

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