

Lantheus Medical Imaging Initiates Phase 3 Clinical Trial of Flurpiridaz F 18 for the Detection of Coronary Artery Disease

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Study to Assess Diagnostic Efficacy of Flurpiridaz F 18 for PET Myocardial Perfusion Imaging Compared to SPECT, the Current Standard of Care

No. BILLERICA, Mass. (June 30, 2011) – [Lantheus Medical Imaging, Inc.](#), a worldwide leader in diagnostic imaging, today announced the initiation of the first of two Phase 3 clinical trials to assess myocardial perfusion using Positron Emission Tomography (PET) imaging with flurpiridaz F 18 in patients with suspected or known coronary artery disease (CAD). The study will evaluate the diagnostic efficacy of flurpiridaz F 18 PET myocardial perfusion imaging (MPI), compared with single photon emission computed tomography (SPECT) MPI in the detection of significant coronary artery disease. The Phase 3 clinical development program will include two open-label trials in approximately 1,350 patients at approximately 100 clinical trial sites worldwide, including locations in the U.S., Canada, Europe and South America.

“The initiation of the first Phase 3 trial with flurpiridaz F 18 marks a critical step in the development of this novel imaging agent and exemplifies our commitment to develop next generation diagnostic imaging products,” said Don Kiepert, President and Chief Executive Officer of Lantheus Medical Imaging. “There is a significant need for improved non-invasive imaging tools to help physicians better evaluate and manage patients with cardiovascular disease. Clinical trial results to date show that PET with flurpiridaz F 18 can improve diagnostic performance compared to SPECT and we anticipate that the results from our Phase 3 clinical program will confirm the findings seen in previous studies, reinforcing the diagnostic efficacy of PET imaging for evaluating coronary artery disease.”

The first Phase 3 clinical trial is an open-label, international multicenter study of flurpiridaz F 18 injection for PET MPI compared to SPECT MPI in patients with suspected or known CAD referred for invasive coronary angiography (ICA). The trial will enroll approximately 680 patients. The primary objective of the study is to assess the diagnostic efficacy (sensitivity and specificity) of flurpiridaz F 18 PET MPI compared to SPECT MPI in the detection of significant CAD as defined by ICA or a documented history of myocardial infarction. Secondary endpoints include the localization of significant CAD, identification of multi-vessel CAD, and the evaluation of image quality, diagnostic certainty, and reversible defect size with flurpiridaz F 18 PET MPI compared to SPECT MPI. Three independent, blinded readers will assess the PET rest and stress images as well as the SPECT rest and stress images for each patient.

“SPECT imaging has a number of challenges, including sub-optimal image quality, underestimation of ischemia, low sensitivity for multi-vessel CAD, and artifacts that result in false positive test results,” said 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, lead investigator of the study. “PET MPI has the potential to reduce the number of patients sent to cardiac catheterization unnecessarily, improve the identification of patients with risky multi-vessel disease, and reduce redundant downstream testing due to non-definitive results.”

Lantheus presented Phase 2 study results for flurpiridaz F 18 at the International Conference on Nuclear Cardiology and Cardiac CT (ICNC10) in May in Amsterdam and at the SNM (Society of Nuclear Medicine) 58th Annual Meeting in June in San Antonio. The findings demonstrated PET myocardial perfusion imaging with flurpiridaz F 18 provided superior image quality, diagnostic certainty, and diagnostic performance for detecting CAD compared to SPECT MPI, the current standard for the non-invasive detection of CAD. The data also demonstrated a strong safety profile for PET imaging with flurpiridaz F 18.

“We are pleased to announce the initiation of the Phase 3 trial with flurpiridaz F 18, which follows on the heels of our Phase 2 data presented at ICNC10 and SNM,” said Dana S. Washburn, M.D., Vice President, Clinical Development and Medical Affairs at Lantheus Medical Imaging. “The results to date with flurpiridaz F 18 suggest that this agent demonstrates improved image quality compared to SPECT and may offer a more thorough evaluation of coronary atherosclerosis and resulting blood flow abnormalities. We believe the Phase 3 study will continue to demonstrate the strong clinical benefits of cardiac PET imaging with flurpiridaz F 18 compared to SPECT.”

The Phase 3 clinical program has received a Special Protocol Assessment from the U.S. Food and Drug Administration. For more information about the flurpiridaz F 18 clinical trial, please visit www.clinicaltrials.gov and reference trial number

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. CAD is the most common form of heart disease, affecting approximately 16.8 million people in the United States². CAD is the leading cause of death in the United States for both men and women³. 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 procedure⁴ 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 structure⁵. 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 disease⁶. Although single-photon emission computer tomography (SPECT) is most commonly used for MPI⁷, 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 stratification⁸.

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 commercializing 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, TechnoLite® (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 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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