

Lantheus Medical Imaging Receives Special Protocol Assessment Approval from FDA for Phase 3 Trial of Flurpiridaz F-18 for the Diagnosis of Coronary Artery Disease

March 11, 2011 12:29 PM ET

Company Anticipates Initiating Phase 3 Trial in the Second Quarter of 2011

No. BILLERICA, Mass. (March 11, 2011) – [Lantheus Medical Imaging, Inc.](#), a worldwide leader in diagnostic imaging, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design and planned analysis of a Phase 3 clinical trial for the assessment of myocardial perfusion using Positron Emission Tomography (PET) imaging of flurpiridaz F-18 in patients with suspected or known coronary artery disease (CAD). The Company plans to initiate the first of two planned Phase 3 trials in the second quarter of 2011.

“The SPA agreement is a significant milestone in the development of flurpiridaz F-18 and provides us with a clearly defined path forward for the Phase 3 program,” said Don Kiepert, President and Chief Executive Officer of Lantheus Medical Imaging. “We thank the FDA for their timely review and approval of this SPA and look forward to initiating the Phase 3 program and building on the clinical trial results to date for this agent. We believe that flurpiridaz F-18 can improve the diagnosis and evaluation of coronary artery disease, ultimately reducing the need for additional medical tests and procedures.”

Flurpiridaz F-18 has completed a Phase 2 clinical trial, and analysis of the full data set will be presented at ICNC10 - Nuclear Cardiology and Cardiac CT Conference scheduled for May 15-18, 2011 in Amsterdam, Netherlands. Preliminary Phase 2 data were presented at the Annual Meeting of the Society of Nuclear Medicine (SNM) in June 2010. These data showed that PET imaging with flurpiridaz F-18 provided better image quality than technetium-99m sestamibi single photon emission computed tomography (SPECT), the current standard for the non-invasive detection of CAD. No serious adverse events attributable to flurpiridaz F-18 injection were reported in Phase 1 or Phase 2 clinical trials. Numerous other abstracts based on single-center evaluation of flurpiridaz F-18 data were presented at various medical conferences in 2010.

“The results of the Phase 2 study with flurpiridaz F-18 are promising and we look forward to presenting the full data analysis later this year and initiating the Phase 3 program,” said Dana S. Washburn, M.D., Vice President, Clinical Development and Medical Affairs at Lantheus Medical Imaging. “Our Phase 3 program demonstrates our ongoing commitment to developing first-in-class imaging tools to advance patient care, and we remain dedicated to investigating the potential of PET technology for evaluating cardiovascular disease.”

The Phase 3 clinical development program will include two open-label trials designed to assess myocardial perfusion using PET imaging of flurpiridaz F-18 in approximately 1,350 patients with suspected or known CAD at approximately 100 clinical trial sites, including locations in the U.S., Canada, Europe and South America. The primary objective of the study will be to assess the diagnostic efficacy (sensitivity and specificity) of flurpiridaz F-18 injection PET myocardial perfusion imaging (MPI), compared with SPECT MPI in the detection of significant coronary artery disease.

About Special Protocol Assessments

A Special Protocol Assessment (SPA) is an agreement between the sponsor and the FDA indicating that the sponsor's proposed trial protocol, including clinical endpoints and statistical analyses, are acceptable to support regulatory approval of the treatment being evaluated. FDA approval for the product is dependent on efficacy results, adverse event profiles and an evaluation of the benefit/risk of a treatment as demonstrated in the [clinical trials](#).

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 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, Technel® (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.

¹ Yalamanchili, P, Wexler, E, Hayes, M, Yu, M, MD, Bozek J, Radeke, H, Azure, M, Purohit, A, Casebier, DS, and Robinson, SP. Mechanism of uptake and retention of 18F BMS-747158-02 in cardiomyocytes: A novel PET myocardial imaging agent. *Journal Nuclear Cardiology* 2007 Nov-Dec;14(6):782-8.

² Cleveland Clinic. Coronary Artery Disease – Risk Factors. <http://my.clevelandclinic.org/heart/prevention/riskfactors.aspx>. Accessed on March 8, 2010.

³ National Institutes of Health, National Heart, Lung, and Blood Institute. Coronary Artery Disease: Who Is At Risk. http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_WhoIsAtRisk.html. Accessed on March 1, 2011.

⁴ Radiology Info. What is Positron Emission Tomography – Computed Tomography (PET/CT) Scanning. <http://www.radiologyinfo.org/en/info.cfm?pg=PET>. Accessed on June 4, 2010.

⁵ National Institutes of Health. NIH Clinical Center. Positron Emission Tomography Department Overview. <http://clinicalcenter.nih.gov/pet/>. Accessed on June 4, 2010.

⁶ Society of Nuclear Medicine. Procedure Guidelines for Myocardial Perfusion Imaging. Version 3.0 June 2002. http://interactive.snm.org/docs/pg_ch02_0403.pdf.

⁷ Salerno, M and Beller, GA, Noninvasive Assessment of Myocardial Perfusion. *Circ Cardiovasc Imaging*. 2009; 2:412-424.

⁸ Heller, G, Calnon, D and Dorbala, S. Recent Advances in Cardiac PET and PET/CT Myocardial Perfusion Imaging. *J Nucl*

Cardiol 2009; 16:962-9.