

Lantheus Medical Imaging to Proceed with Flurpiridaz F 18 Phase 3 Clinical Program Based on Interim Analysis of Data from First Phase 3 Study

May 1, 2013 5:05 PM ET

No. BILLERICA, Mass. (May 1, 2013) – [Lantheus Medical Imaging, Inc.](#), a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced an important milestone for its Phase 3 flurpiridaz F 18 clinical program. An interim analysis of the first of two Phase 3 studies has met the criteria for completion.

“The interim analysis was an important achievement on the way to bringing this potentially game-changing agent to market,” said Jeff Bailey, President and CEO, Lantheus Medical Imaging.

To date, approximately 900 subjects have been imaged with flurpiridaz F 18. The Phase 2 clinical study for flurpiridaz F 18 established optimal rest and stress protocols and indicated that the agent has a superior profile over single photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI). The Phase 3 clinical development program includes two trials in approximately 1,400 patients at clinical trial sites in North America and Europe. Both Phase 3 clinical studies have received a Special Protocol Assessment from the U.S. Food and Drug Administration. The primary objective of the Phase 3 clinical program is to assess myocardial perfusion using Positron Emission Tomography (PET) imaging with flurpiridaz F 18 in patients with known or suspected coronary artery disease (CAD). The first of the two Phase 3 studies has passed the interim analysis assessment milestone and should be completed later in the year. For more information about the flurpiridaz F 18 clinical trial, please visit www.clinicaltrials.gov and reference trial number NCT01347710.

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 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. MPI is a non-invasive test that utilizes a small amount of radioactive material (radiopharmaceutical) injected into the body to show 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 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 global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The Company’s proven success in the field of diagnostic imaging provides a strong platform from which to bring forward breakthrough tools for the diagnosis and management of disease. Lantheus imaging products include the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an ultrasound contrast agent for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border, Technelite® (Technetium Tc 99m Generator), Cardiolute® (Kit for the Preparation of Technetium Tc 99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride Tl 201 Injection). Lantheus has approximately [550] 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 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 April 2013.

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 April 2013.

⁴ Radiology Info. What is Positron Emission Tomography – Computed Tomography (PET/CT) Scanning. <http://www.radiologyinfo.org/en/info.cfm?pg=PET>. Accessed April 2013.

⁵ National Institutes of Health. NIH Clinical Center. Positron Emission Tomography Department Overview. <http://clinicalcenter.nih.gov/pet>. Accessed April 2013.

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.