Lantheus Releases Preliminary Results from Phase 3 Clinical Trial of Flurpiridaz F 18 for the Detection of Coronary Artery Disease

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N. BILLERICA, Mass. (October 29, 2013) – Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced preliminary results from the first of two planned Phase 3 trials to assess the diagnostic efficacy of flurpiridaz F 18, an imaging agent used in Positron Emission Tomography (PET) myocardial perfusion imaging (MPI) for the detection of coronary artery disease (CAD). The trial compared PET MPI with flurpiridaz F18 to single photon emission computed tomography (SPECT) MPI, the current standard of care, using invasive coronary angiography as the truth standard. The open-label, multicenter study had two co-primary endpoints: superiority in sensitivity (identifying disease) and non-inferiority in specificity (ruling out disease). Flurpiridaz F 18 outperformed SPECT in a highly statistically significant manner in sensitivity and showed a statistical trend towards improved diagnostic accuracy. However, flurpiridaz F 18 did not meet the non-inferiority criterion for identifying subjects without disease.

"While preliminary results of this trial show that flurpiridaz F 18 missed one of the two co-primary endpoints, when looking at key secondary endpoints, such as image quality and diagnostic certainty, the image quality seen with flurpiridaz F 18 in the study is impressive, both absolutely and in comparison to SPECT, leading to a statistically significant improvement in diagnostic certainty," stated Cesare Orlandi, M.D., F.A.C.C., Lantheus Chief Medical Officer. "Image quality is very important in nuclear cardiology, since it allows diagnosing presence or absence of disease with greater confidence, which may lead to a decreased need for patient re-testing."

"We remain committed to our flurpiridaz F 18 clinical program. Next steps will include further image and data analysis, and meeting with our clinical advisors and the FDA," stated Jeff Bailey, Lantheus President and Chief Executive Officer. "We will explore potential modifications to our clinical development plan and determine how we can use the results of this trial to advance the Phase 3 program for this exciting diagnostic candidate."

"I continue to believe this novel agent is likely to represent the next advance in nuclear cardiology," said lead investigator Jamshid Maddahi, M.D., F.A.C.C., F.A.S.N.C., Professor of Molecular and Medical Pharmacology (Nuclear Medicine) and Medicine (Cardiology) at the David Geffen School of Medicine at UCLA. "Flurpiridaz F 18 has consistently demonstrated an ability to provide higher quality images and superior diagnostic performance than the current standard of care. In this study, the greater PET image resolution may have contributed to missing the non-inferiority specificity endpoint. More importantly, the SPECT results showed surprisingly low sensitivity and elevated specificity which is inconsistent with prior studies, including the flurpiridaz F 18 Phase 2 trial. These findings may have confounded the outcome of the trial. From a safety perspective, the agent appears to be well-tolerated and the prospect of unit dose availability would make this candidate an attractive alternative to currently available diagnostic agents."

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 coronary artery disease (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 women. Each year more than half a million Americans die from CAD3. The flurpiridaz F 18 Phase 2 study results were published in the Journal of the American College of Cardiology (JACC) on January 29, 20134.

About PET and MPI Positron Emission Tomography, also called PET imaging or a PET scan, is a type of nuclear medicine imaging procedure5 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 structure6. 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 disease7. Although SPECT is most commonly used for MPI8, 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 stratification9.

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 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, 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), Cardiolite® (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.

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