Lantheus Medical Imaging, Inc. Presents Preliminary Data on Novel PET Myocardial Perfusion Imaging Agent Protocol at SNM Annual Meeting

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-- Flurpiridaz F 18 Data Determine Parameters for One-Day Rest-Stress Test to Detect Coronary Artery Disease --

N. BILLERICA, Mass. (June 9, 2010) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medical imaging, today announced preliminary Phase 2 data describing the methodology used to define an imaging protocol for a one-day rest-stress myocardial perfusion imaging test using its novel investigational PET imaging agent flurpiridaz F 18 injection (formerly known as BMS747158). Flurpiridaz F 18 injection is in development for use with Positron Emission Tomography (PET) for myocardial perfusion imaging (MPI) to detect coronary artery disease. Data suggest that the uptake properties of flurpiridaz F 18 injection make it possible to allow for a relatively low dosing ratio and a delay of between 30 minutes and one hour between rest and stress injections, depending on the mode of stress used.

Lantheus, together with its partner in this method development, Cardiovascular Imaging Technologies of Kansas City, Mo., developed an innovative technique to determine the dependence of the rest-to-stress dosing ratio in order to identify the minimum delay between the two injections for a one-day rest-stress test. The data were featured today in an oral presentation (# 798451) by Joel Lazewatsky, Ph.D., Principal Research Scientist, Lantheus Medical Imaging, Inc., and in a poster presentation (# 799099) on Tuesday, June 8 by James A. Case, Ph.D., Director of Physics at Cardiovascular Imaging Technologies, at the SNM 57th Annual Meeting in Salt Lake City.
"Our team used data derived from a Phase 2 clinical study of flurpiridaz F18 injection PET MPI to define the optimal delay between rest and stress dosing as part of an effort to determine the lowest total dose needed to obtain good quality images," said Dr. Lazewatsky. "We are currently validating this model with the second cohort of patients from the Phase 2 clinical study and we look forward to the results."

To identify the appropriate amounts of rest and stress dosing for hypothetical same-day rest and stress dosing, computer simulations of same-day rest and stress images were developed using actual rest and stress image data obtained from 20 patients who were each imaged on a two-day basis. The actual rest and stress images from the separate days together with the computer simulations of same-day images were each reviewed in a blinded fashion by three experienced readers.

In evaluating the maximum residual contribution of the imaging agent initially used in the rest study to the subsequent stress image which did not produce a meaningful change in the reader's perception of the stress image, it was determined for stress induced by adenosine (a pharmacological stress agent) that a minimum dosing ratio of 2.0 (twice as much imaging agent used in stress as compared to rest) was required with a 30 minute delay between injections. For stress induced by exercise, a minimum dosing ration of 3.0 (three times as much imaging agent used in stress as compared to rest) was needed with a one hour delay between injections.

"Using this novel approach, we expect to validate a protocol that fits into current clinical practice and that can be administered at the lowest possible dose for patients undergoing a same-day rest-stress test with flurpiridaz F 18 injection," said Dana Washburn, M.D., Vice President, Clinical Development and Medical Affairs, Lantheus Medical Imaging, Inc. "We developed this novel methodology to define the rest and stress doses as well as the optimal delay between the two doses without having to involve a large number of patients."

Drs. Lazewatsky and Case led the collaboration between Lantheus and Cardiovascular Imaging Technologies to develop this unique approach to protocol optimization. "This novel approach of modeling different dosages and time intervals based on baseline image data not only enabled recognition of optimal acquisition parameters for image quality and dosimetry, but dramatically shortened development time that otherwise would have depended on trial and error methodology," said Dr. Case.

About Flurpiridaz F 18 Injection
Flurpiridaz F 18 injection, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1), was designed to be a novel myocardial perfusion PET imaging agent for the diagnosis of coronary artery disease (CAD). The agent is currently in Phase 2 clinical development. CAD is the leading cause of death in the United States for both men and women[1]. Each year, more than half a million Americans die from CAD[1].

In Phase 1 clinical studies, flurpiridaz F 18 injection was well-tolerated and demonstrated radiation dosimetry that suggests that good quality images may be obtained with patient radiation doses that are within accepted limits. The data also showed high myocardial uptake at rest that significantly increased with pharmacologically induced stress as well as a ratio of myocardial to background uptake that was favorable and improved over time, suggesting encouraging potential as a myocardial perfusion PET imaging agent for patients both at rest and under stress.

About PET and MPI

Positron emission tomography, also called PET imaging or a PET scan, is a type of nuclear medicine imaging procedure[2] 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[3]. 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[4]. MPI is used to identify areas of reduced blood flow (perfusion) to the heart muscle[4]. 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[4]. Although single-photon emission computer tomography (SPECT) is most commonly used for MPI[5], 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[6].

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 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. For more information, visit www.lantheus.com.

About Cardiovascular Imaging Technologies, LLC.

Cardiovascular Imaging Technologies, LLC. is based in Kansas City, Missouri. CVIT's business interests include development of cardiac imaging software, core imaging lab functions, new-agent consulting, technical support services, and research support for Phases 1 through 4 investigations. Its core lab specializes in modeling early Phase 1 and Phase 2 studies to help design more scientific and accurate later stage clinical trials. The core lab also specializes in site training and quality maintenance during later phase studies to insure data consistency across a broad range of investigator instrumentation. It is a recognized pioneer in the evolution of myocardial perfusion PET. Its processing, quality control, and myocardial perfusion quantitation software is used by more than 50% of PET centers that regularly perform myocardial perfusion imaging.

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2. 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.

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6. 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.