New Study Published in the *Journal of Nuclear Cardiology* Explores the Utility of Spect Myocardial Perfusion Imaging with Cardiolite® in Patients with New-Onset of Heart Failure

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Multi-National Prospective Study Findings Shed Light on SPECT's Performance Characteristics for the Diagnosis of Coronary Artery Disease in Patients with New-Onset Heart Failure.

N. BILLERICA, Mass. (January 27, 2009) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, announced today new data from a prospective, non-randomized, multi-national study that shows gated single-photon emission computed tomographic (SPECT) myocardial perfusion imaging (MPI) with Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) had a 96 percent negative predictive value for diagnosing extensive coronary artery disease in patients hospitalized with their first episode of heart failure. These study findings were published in the January/February 2009 issue of *The Journal of Nuclear Cardiology.*

More than 5 million Americans are living with heart failure[1] – a chronic condition in which the heart can no longer pump enough blood to the rest of the body.[2] Each year 550,000 new cases of heart failure are diagnosed.[3] One of the most common causes of heart failure is coronary artery disease (CAD).[4] Data from observational studies suggest that CAD is the underlying cause of up to 70 percent of patients with heart failure.[5] CAD is the leading cause of death in the United States for both men and women,[6] with more than half a million Americans dying from CAD each year.6 MPI is often used to determine the presence and severity of physiologically significant CAD in patients with suspicious symptoms.[7] This is the first study to explore myocardial perfusion imaging's diagnostic utility specifically in patients with new-onset heart failure.

"Because some patients with heart failure and extensive coronary artery disease may benefit from coronary revascularization and improve their quality of life and longevity, identifying the extent and severity of underlying CAD in these patients is a critical first step in the initial management of their care. As the first study to examine the utility of SPECT MPI for CAD detection in patients with new-onset heart failure, these results are very encouraging and point to gated SPECT as a potentially useful diagnostic modality for heart failure patients without angina or other clinical indicators of CAD," said Prem Soman, M.D., Ph.D., F.R.C.P., associate director of nuclear cardiology, University of Pittsburgh Medical Center, Presbyterian University Hospital and lead author of The Investigation of Myocardial Gated SPECT Imaging in Heart Failure (IMAGING in HF) trial.

A normal stress SPECT MPI indicates a very low probability of extensive CAD in patients with heart failure, and therefore, invasive coronary angiography can be avoided. "These initial findings point to the need for further evaluation of the use of SPECT MPI for CAD detection in new-onset heart failure patients," continued Dr. Soman.

The IMAGING in HF study was designed to explore the role of gated SPECT MPI using Cardiolite® as an initial investigative strategy for diagnosing extensive CAD, which is potentially etiologically relevant to patients hospitalized with their first episode of heart failure. The observational study assessed 201 patients hospitalized with their first presentation of heart failure at 14 sites in the United States and the United Kingdom. All patients received a stress and rest SPECT MPI test using Cardiolite®. Data was analyzed in a core laboratory and provided researchers with 99.5 percent interpretable stress images and 98.5 percent interpretable rest and stress images. Coronary arteriography was performed when clinically indicated.

SPECT MPI had 96 percent sensitivity, 56 percent specificity and a 96 percent negative predictive value for the diagnosis of extensive CAD, defined conventionally as $\geq$ 70 percent stenosis in two or more major epicardial coronary arteries, or $\geq$ 70 percent in the left main coronary artery /proximal left anterior descending coronary artery, or single vessel disease with prior myocardial infarction or coronary revascularization. The diagnostic values of SPECT MPI for more limited CAD were 82 percent sensitivity, 57 percent specificity and 75 percent negative predictive value. These definitions were used to differentiate heart failure patients with extensive, etiologically relevant CAD from those with more limited, co-existing CAD. The presence of extensive CAD indicates a causal relationship with heart failure and such patients are likely to benefit from coronary revascularization.

"The current professional society guidelines provide physicians with mixed direction regarding diagnostic procedures for patients with new-onset heart failure," said James Udelson, M.D., principal investigator of the study and chief of cardiology at Tufts Medical Center in Boston. "These study findings build additional clinical evidence for the use of SPECT MPI with Cardiolite® as a noninvasive procedure, prior to more invasive coronary angiography, to help physicians assess and select which patients would benefit most from revascularization."

“Only 12% of patients had active anginal symptoms, making a CAD diagnosis difficult on clinical grounds, and increasing the importance of using imaging tests such as Cardiolite®. These study findings further demonstrate the expanding role that SPECT imaging with Cardiolite® plays in risk stratification for patients with their first episode of heart failure,” said Mark Hibberd, M.D. Ph.D., senior medical director, global medical affairs, Lantheus Medical Imaging, Inc. “Lantheus’ support of this study reaffirms our ongoing commitment to and long-standing heritage in fostering innovation in cardiac imaging and providing important clinical information that helps physicians better manage their patients’ care.”

About Cardiolite®

Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) is one of the world’s most widely-used cardiac imaging agents and the only technetium labeled myocardial perfusion agent that has been used to image more than 40 million patients. For almost two decades, Cardiolite® has played a vital role in the diagnosis and management of patients with known or suspected coronary artery disease.

Cardiolite® is the first technetium labeled myocardial perfusion tracer to provide physicians with prognostic information that can be helpful in making patient management decisions. Cardiolite® is the subject of more than 10,000 publications and the imaging agent of choice within several post marketing cardiology clinical trials – DIAD, BARI-2D, COURAGE, ERASE, INSPIRE and CHRISTMAS – which have resulted in changes in patient care. Cardiolite® leads the way with the most FDA approved clinical indications as a myocardial perfusion imaging agent.

Indication and Important Safety Information Regarding Cardiolite®

Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. Cardiolite® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

Exercise and pharmacologic stress testing should be performed only under the supervision of a qualified physician. Cardiolite® has been rarely associated with acute severe allergic events of angioedema and urticaria. The most frequently reported adverse events include headache, chest pain/angina, ST segment changes on ECG, nausea, and abnormal taste and smell.

For full prescribing information, please visit www.cardiolite.com. Cardiolite® is a registered trademark of Lantheus Medical Imaging, Inc.

About Single-Photon Emission Computerized Tomography (SPECT)

A single-photon emission computerized tomography (SPECT) scan is a nuclear imaging technique that involves injecting a radioactive liquid into the blood, then taking a series of pictures around the chest.[8] A SPECT scan produces three-dimensional images that show how organs function.[9] For myocardial perfusion imaging, single photon emission tomography (SPECT) remains the dominant modality at this time.[10]

About Myocardial Perfusion Imaging (MPI)

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.[11] MPI is used to identify areas of reduced blood flow to the heart muscle4 to determine whether or not the heart is working properly. Following the administration of the radiopharmaceutical, the heart rate is raised to induce myocardial stress, either by exercise or pharmacologically.[12] Using SPECT technology, images of the heart muscle are then obtained and examined.

About Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 50 years, is committed to advancing the field of diagnostic imaging. The company’s proven success in discovering, developing and marketing innovative medical imaging agents provides an unparalleled platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. The company is home to leading diagnostic imaging brands, including Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection), DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension, and

TechneLite® (Technetium Tc99m Generator) and has nearly 700 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada, and Australia. For more information, visit www.lantheus.com

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[3] American Heart Association. Heart Failure. http://www.americanheart.org/presenter.jhtml?identifier=1486

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[5] Gheorgiade M, Bonow RO. Chronic heart failure in the United States.: A manifestation of coronary artery disease. Circulation 1998;97:282-9

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

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[9] Mayo Clinic. SPECT scan.

[10] Glover, David K and Gropler, Robert J. Editorial: Journey to find the ideal PET flow tracer for clinical Use: Are we there yet? J Nucl Cardiology 2007;14:765-8

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

[12] Wikipedia. Definition of myocardial perfusion imaging. http://en.wikipedia.org/wiki/SPECT

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