BARI 2D Study Presented at American Diabetes Association Scientific Sessions Underscores Utility of Spect Myocardial Perfusion Imaging in Identifying Cardiovascular Risk and Evaluating Treatment Outcomes for Patients with Type 2 Diabetes

June 12, 2009 3:50 PM ET

Pivotal Trial Demonstrates Importance of Diagnostic Imaging for Type 2 Diabetes Patients with Coronary Artery Disease to Determine Appropriate Patient Care

N. BILLERICA, Mass. (June 12, 2009) - Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today recognizes and comments on the primary outcome findings of The Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) study presented at the American Diabetes Association's 69th Scientific Sessions and published in the June 11, 2009 issue of the *New England Journal of Medicine*. The clinical trial examined the impact of cardiac treatment approaches in patients with type 2 diabetes and documented stable coronary artery disease (CAD), and underscores the clinical value of single-photon emission computerized tomography (SPECT) myocardial perfusion imaging (MPI) with Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) in identifying risk and managing cardiovascular outcomes for this patient population.

Datafrom the landmark, multicenter, randomized, longitudinal trial of 2,368 patients found that there was no significant difference in five-year survival rates among patients who received revascularization (88.3 percent) compared to drug therapy alone (87.8 percent). However, in the patient group who were pre-identified as candidates for coronary bypass surgery the rate of all major cardiovascular events (heart attacks, strokes and death) was significantly lower (22.4 percent) compared to those who received drug therapy alone (30.5 percent).

One of the two primary objectives for the BARI 2D study was to determine if a strategy of initial elective coronary revascularization by either bypass surgery or angioplasty combined with aggressive medical therapy results in a lower five-year mortality compared with a strategy of initial aggressive medical therapy alone. The two coronary revascularization procedures were not compared to each other; but rather each treatment group was independently compared to its own control group receiving intensive medical therapy alone.

Cardiolite® was used as the SPECT imaging agent of choice to objectively identify CAD during initial patient recruitment and for subsequent one, three and five-year follow-up of patients enrolled in the study. In particular, patients in the study underwent SPECT MPI with Cardiolite® to determine the impact of therapy approaches on left ventricular ejection fraction (LVEF), ischemia burden and scar.

"More than 25 percent of patients with diabetes have severe myocardial ischemia, myocardial infarction or both, without exhibiting chest pain or chest discomfort[1]; thus, diagnosis of CAD may be difficult without diagnostic imaging. Early detection and risk stratification of CAD in type 2 diabetes patients is critical to successfully manage and prevent further cardiovascular complications," said Mark Hibberd, M.D., Ph.D., senior medical director, global medical affairs, Lantheus Medical Imaging, Inc. "The BARI 2D findings reinforce the clinical value of SPECT MPI in determining the extent and severity of myocardial ischemia in patients with type 2 diabetes and stable CAD."

The BARI 2D study was conducted by the University of Pittsburgh Graduate School of Public Health Epidemiology Data Center in collaboration with 49 clinical sites in the United States and abroad. The National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, were sponsors of the study.

"The BARI 2D study findings build additional clinical evidence on the important association between CAD and type 2 diabetes ," said Don Kiepert, president and chief executive officer of Lantheus Medical Imaging, Inc. "As leaders in diagnostic imaging, we strongly support studies of this magnitude that advance the standard of care in patients with type 2 diabetes."

About Type 2 Diabetes and Coronary Artery Disease (Heart Disease)
Approximately 24 million adults or 7.8 percent of the American population has diabetes.[2] In adults, type 2 diabetes accounts for about 90 percent to 95 percent of all diagnosed cases of diabetes.[3] Heart disease is a major complication and leading cause of premature death among people with diabetes.[4] In particular, people with type 2 diabetes have two-to-four-fold higher rates of heart disease.[5]

About Single-Photon Emission Computerized Tomography (SPECT)
A single-photon emission computerized tomography (SPECT) scan is a nuclear imaging technique that involves injecting a

radiopharmaceutical into the blood, then taking a series of pictures.[6] A SPECT scan produces three-dimensional images that show how organs function.[7] For myocardial perfusion imaging, single photon emission tomography (SPECT) remains the dominant modality at this time.[8]

About Myocardial Perfusion Imaging

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.[9] MPI is used to identify areas of reduced blood flow to the heart muscle to determine whether or not the heart is working properly. The test has two parts; rest and stress. The radiopharmaceutical is administered intravenously at rest and again during exercise or pharmacologic stress with images taken during each part of the test. The physician then examines and compares the two image sets.

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, COURAGE, ERASE, INSPIRE and CHRISTMAS – which have resulted in changes in patient care.

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 Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 50 years, is committed to advancing and investing in the field of diagnostic imaging. The company's proven success in discovering, developing and marketing innovative medical imaging agents provides a solid platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. The company is home to leading cardiac 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 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.

[1] Cook SA et al. (2005) Therapy insight: heart disease and the insulin-resistant patient. Nat Clin Pract Cardiovasc Med 2: 252-259

[2] American Diabetes Association. http://www.diabetes.org/about-diabetes.jsp

[3] Centers for Disease Control and Prevention. National diabetes fact sheet, 2007. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf.

[4] Centers for Disease Control and Prevention. Centers for Disease Control and Prevention: Diabetes surveillance report, 1999. Atlanta, GA: US Department of Health and Human Services, 1999.

[5] Roman SH, Harris MI. Management of diabetes mellitus from a public health perspective. Endocrinol Metab Clin North Am 1997: 26:443-74.

[6] American Heart Association. Cardiac Glossary. http://www.americanheart.org/presenter.jhtml?identifier=3038599

[7] Mayo Clinic. SPECT scan.

[8] 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.

[9] Society of Nuclear Medicine. Procedure guidelines for myocardial perfusion imaging. Version 3.0 June 2002 http://interactive.snm.org/docs/pg_ch02_0403.pdf.