Lantheus Medical Imaging, Inc. Completes Enrollment of Cares Registry to Further Evaluate Definity® in Patients with Suboptimal Echocardiograms

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Over 1,000 Patients Enrolled in First-Of-Kind US Study

N.BILLERICA, Mass. (May 28, 2009) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announces that it has completed patient enrollment of CaRES (**C**ontrast Echoc**a**rdiography **RE**gistry for **S**afety Surveillance), the first, multicenter Phase IV observational registry that evaluates the use of ultrasound imaging agents in routine clinical practice. The 1,060 patients who were enrolled at 15 sites in the U.S. were 18 years old or older and required DEFINITY® Vial for (Perflutren Lipid Microsphere) injectable suspension-enhanced echocardiography because of a previous suboptimal, unenhanced echocardiogram.

"As the first, multicenter safety registry of its kind to be conducted in the U.S., the results from CaRES will provide important clinical information about the use of DEFINITY® in a range of patient types and clinical settings," said Mark Hibberd, M.D., senior medical director, Lantheus Medical Imaging, Inc. "We are excited to complete enrollment of this important study and look forward to gaining new insights regarding the use of DEFINITY® in routine clinical practice. We expect these findings to reveal that DEFINITY® is being used in the settings recommended in the recent American Society of Echocardiography Consensus Statement[1], and that these uses are well tolerated. The use of DEFINITY® in appropriate settings, such as in-hospital and intensive care units, can assist physicians in making immediate point-of-care decisions, as recently shown by Kurt et al[2] and in doing so, can help reduce the use of other more costly tests and direct medical therapy to meet patient needs."

The CaRES registry was established following discussions with the FDA to further explore the clinical use of DEFINITY®. The prospective, open-label, non-randomized, Phase IV surveillance registry will gather and analyze data on: patient demographics and characteristics, reasons for using DEFINITYÒ, results of safety monitoring, and the nature and frequency of any adverse events.

"Since DEFINITY® received approval for use in the U.S., approximately two million doses have been administered to patients with suboptimal echocardiograms to see the borders of the heart more clearly. Recent articles published in the *American Journal of Cardiology*[3] and the *Journal of the American College of Cardiology*[4] have highlighted the clinical benefit of DEFINITY® in lowering the risk of short-term mortality and improving diagnostic evaluations for patients receiving contrast-enhanced echocardiograms," said Don Kiepert, president and CEO of Lantheus Medical Imaging, Inc. "With the completion of enrollment of the CaRES registry, Lantheus continues our ongoing commitment to providing important clinical information on the use of DEFINITY® to the physician community."

About Suboptimal Echocardiograms

Up to 20 percent of resting echocardiography studies will result in suboptimal echocardiograms.[5],[6],[7] A suboptimal image is one in which at least 2 out of 6 myocardial segments of the left ventricle cannot be visualized appropriately, as defined by the American Society of Echocardiography (ASE).[8],[9] The use of contrast in suboptimal echocardiograms may help with clinical evaluation of the patient.[10],[11]

About DEFINITY®

Since its launch in 2001, activated DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension has been administered to over two million patients.[12] In patients with suboptimal echocardiograms, DEFINITY® enables physicians to visualize the borders of the heart more clearly.[13],[14]

Indications

Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. The safety and efficacy of DEFINITY® with exercise stress or pharmacologic stress testing have not been established. For full prescribing information, please visit www.lantheus.com.

Important Safety Information About DEFINITY®

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration.

- Assess all patients for the presence of any condition that precludes DEFINITY® administration (see CONTRAINDICATIONS).
- In patients with pulmonary hypertension or unstable cardiopulmonary conditions, monitor vital sign measurements, electrocardiography and cutaneous oxygen saturation during and for at least 30 minutes after DEFINITY® administration (see WARNINGS).
- **Always have resuscitation equipment and trained personnel readily available.**

Do not administer DEFINITY® to patients with known or suspected cardiac shunts (right-to-left, bi-directional or transient right-to-left), or hypersensitivity to perflutren. Do not administer DEFINITY® by intra-arterial injection.

In postmarketing use, uncommon but serious reactions observed during or shortly following perflutren-containing microsphere administration included fatal cardiac or respiratory arrest, loss of consciousness, convulsions, symptomatic arrhythmias (atrial fibrillation, supraventricular tachycardia, ventricular tachycardia or fibrillation), hypotension, respiratory distress or cardiac ischemia (see ADVERSE REACTIONS). The risk for these reactions may be increased among patients with pulmonary hypertension or unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, serious ventricular arrhythmias or respiratory failure, including patients receiving mechanical ventilation). In the absence of these underlying conditions, observe patients closely during and following DEFINITY® administration.

Always have cardiopulmonary resuscitation personnel and equipment readily available prior to DEFINITY® administration and monitor all patients for acute reactions.

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 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.

[1] Mulvagh SL et al. American Society of Echocardiography consensus statement on the clinical applications of ultrasonic contrast agents in echocardiography. *J Am Soc Echocardiogr*. 2008; vol. 21 no. 11: 1179-1201

[2] Kurt M et al. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospect cohort. *J Am Coll Cardiol*. 2009; 53: 802-810

[3] Main ML et al. Acute mortality in hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent (multicenter registry results in 4,300,966 consecutive patients). *Am J Cardiol*. 2008; vol. 102, issue 12: 1742-1746

[4] Kurt M et al. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospect cohort. *J Am Coll Cardiol*. 2009; 53: 802-810

[5] Mulvagh SL et al. Contrast echocardiography: current and future applications. *J Am Soc Echocardiogr*. 2000; 13: 331-42

[6] Waggoner AD et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: recommendations of the American Society of Echocardiography Council on Cardiac Sonography. *J Am Soc Echocardiogr*. 2001; 14: 417-420

[7] Solomon S, *Essential echocardiography, a practical handbook with DVD*. Humana Press; 2007: chapter 5: ventricular systolic function, p 113

[8] Mulvagh SL et al. Contrast echocardiography: current and future applications. *J Am Soc Echocardiogr* 2000; 13: 331-42

[9] Waggoner AD et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: recommendations of the American Society of Echocardiography Council on Cardiac Sonography. *J Am Soc Echocardiogr* 2001; 14: 417-420

[10] Mulvagh SL et al. Contrast echocardiography: current and future applications. *J Am Soc Echocardiogr* 2000; 13: 331-42

[11] Kitzman DW et al. Efficacy and safety of the novel ultrasound contrast agent perflutren (Definity) in patients with suboptimal baseline left ventricular echocardiographic images. *Am J Cardiol*. 2000; 86: 669-674

[12] Source:*The Echocardiography Monthly Monitor: United States, October 2001-September 2007*, Arlington Medical Resources, Inc., Malvern, PA.

[13] Kitzman DW et al. Efficacy and safety of the novel ultrasound contrast agent perflutren (Definity) in patients with suboptimal baseline left ventricular echocardiographic images. *Am J Cardiol*. 2000; 86: 669-674

[14] Data on file, Lantheus Medical Imaging, Inc.