Lantheus Medical Imaging, Inc. Presents Phase 4 Safety Data on DEFINITY® at American Society of Echocardiography Annual Meeting

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-- Findings Showed No Significant Changes in Pulmonary Artery Hemodynamics in Patients With Normal or Elevated Pulmonary Artery Pressure Undergoing Contrast Echocardiography With DEFINITY® --

N. BILLERICA, Mass. (June 14, 2010) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medical imaging, today announced new data from a Phase 4, open-label safety study evaluating the effect of DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension, an echocardiography contrast agent, on pulmonary and systemic artery hemodynamics in patients with either normal or increased baseline pulmonary artery pressure. The study demonstrated that administration of DEFINITY® did not result in any clinically or statistically significant changes in systemic or pulmonary artery hemodynamic measurements in either patient group. The data were presented on Sunday, June 13, 2010, by Kevin Wei, M.D., Associate Professor of Medicine at Oregon Health & Science University, during the "Contrast Perfusion Imaging in Decision-Making" case-based presentation at the American Society of Echocardiography 21st Annual Scientific Sessions in San Diego.

"Examining changes in pulmonary pressures following the administration of ultrasound contrast imaging agents is an important safety measurement," said Dr. Wei. "This Phase 4 safety evaluation demonstrated that the administration of DEFINITY® produced no changes in pulmonary or systemic hemodynamic parameters, either in patients with normal or increased pulmonary artery pressure at baseline, providing further validation of the safety profile of this agent."

The primary objective of this study was to evaluate the effect of DEFINITY® on pulmonary artery hemodynamics in patients with normal or elevated baseline pulmonary artery pressure who were undergoing right heart catheterization as part of routine clinical evaluation. The study's secondary objective was to assess the safety and potential immunologic effects of DEFINITY® administration in these patients.

The Phase 4, open-label, non-randomized study was conducted at eight sites in the United States and enrolled 34 patients, 32 of whom received DEFINITY®. DEFINITY® was administered after right heart catheterization had been initiated and pulmonary artery systolic pressure (PASP) and additional baseline measurements had been obtained. Safety assessments, including multiple pulmonary artery hemodynamic measurements and serum blood testing for immune response were conducted up to 60 ± 10 minutes after DEFINITY® administration. Patients were contacted up to 24 + 8 hours after the administration of DEFINITY® to perform adverse event (AE) monitoring and at 4 + 3 days for serious adverse event (SAE) monitoring.

DEFINITY® administration did not result in any clinically or statistically significant changes in systemic and pulmonary artery hemodynamic measurements in the patients with either normal or elevated PASP in the population tested. Overall, DEFINITY® demonstrated a positive safety profile and was well tolerated. No deaths, SAEs or other significant AEs occurred during the study. Results of the immunologic tests showed no evidence for hypersensitivity reactions in any patient. Additionally, there were no clinical events that suggested evidence of mast cell activation or hypersensitivity reactions related to DEFINITY® administration.

"This study shows that DEFINITY® is well tolerated and can be used in patients with normal and elevated PASP without causing abnormalities in pulmonary artery hemodynamics or triggering immunologic changes or hypersensitivity reactions. These findings reinforce the safety of DEFINITY®-enhanced echocardiography in routine clinical practice," said Dana Washburn, M.D., Vice President, Clinical Development and Medical Affairs, Lantheus Medical Imaging, Inc. "This Phase 4 safety study marks Lantheus' third and final post-approval, FDA-required safety study for DEFINITY®, and illustrates that DEFINITY® can be used in patients with or without pulmonary hypertension when contrast is needed to enhance suboptimal echocardiograms."

In 2009, Lantheus completed the first two safety commitments, the CaRES (Contrast echocardiography REgistry for Safety Surveillance) prospective safety registry among 1,053 patients undergoing contrast and a retrospective observational study of safety in 15,798 critically ill patients undergoing DEFINITY® echocardiography in the ICU setting.

"Lantheus is the first microbubble ultrasound contrast manufacturer to initiate and complete these important safety studies the FDA has requested of all manufacturers," said Mark G. Hibberd, M.D., Ph.D., Senior Medical Director, Medical Affairs and Pharmacovigilance, Lantheus Medical Imaging, Inc. "The results of Lantheus' studies confirm that DEFINITY® can be used

when baseline echocardiograms are suboptimal in a broad range of outpatient and inpatient care settings, including those who are critically ill in the ICU setting, and those who have pre-existent pulmonary hypertension."

About DEFINITY®
DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension is an ultrasound contrast agent for use in patients with suboptimal cardiograms (see Indications below)[1,2]. Since its launch in 2001, activated DEFINITY® has been administered to over 2.5 million patients[3]. Given that up to 20 percent of resting echocardiography studies will result in suboptimal echocardiograms[4,5,6], the use of a contrast agent may reduce the need for subsequent testing[1,7].

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.

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

IMPORTANT SAFETY INFORMATION

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.**

In post marketing use, rare but serious cardiopulmonary or anaphylactoid reactions have been reported during or shortly following perflutren-containing microsphere administration (see ADVERSE REACTIONS). The risk for these reactions may be increased among patients with pulmonary hypertension or unstable cardiopulmonary conditions. It is not always possible to reliably establish a causal relationship to drug exposure due to the presence of underlying cardiopulmonary disease.

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.

1. 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.

2. Data on file, Lantheus Medical Imaging, Inc.
3. Source: *The Echocardiography Monthly Monitor: U.S. Editions, 2002 - 2009,* Arlington Medical Resources, Inc., Malvern, PA.
4. Mulvagh SL et al. contrast Echocardiography: Current and future applications. *J Am Soc Echocardiogr* 2000; 13:331-42.
5. Waggoner AD, et al, Guidelines for the cardiac sonographer in the performance of contrast echocardiography. *J Am Soc Echocardiogr.* 2001: 417-420.
6. Edited by Scott D. Solomon, MD, Essential Echocardiography, A Practical handbook with DVD. Humana Press; 2007 Chapter 5: Ventricular Systolic function, P113.
7. Shaw LJ et al. Clinical and economic outcomes assessment with myocardial contrast echocardiography. *Heart* 1999; 82(Suppl III): III16-III21.