Lantheus Medical Imaging Updates Definity® Label to Modify Benefit/Risk Assessment of the Product

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- FDA Approves Class Labeling Changes For Echo Contrast Agents -

N. Billerica, MASSACHUSETTS (May 13, 2008) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced important changes to the U.S. product label for DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension. Based on an extensive and thorough review of recent safety information provided to the FDA by both Lantheus and members of the echocardiography community, the Prescribing Information revisions modify DEFINITY®'s benefit/risk assessment. The DEFINITY® label changes the FDA approved today supercede the FDA-mandated label changes that Lantheus announced in October 2007 and include revisions to the boxed WARNING, WARNINGS and CONTRAINDICATIONS sections of the prescribing information. Similar label updates have been approved by the FDA for all perflutren-containing microsphere contrast agents.

"Educational outreach by the echocardiography community to the FDA was instrumental in achieving this class label change. These important changes provide clearer guidance to healthcare providers regarding product safety monitoring and contraindications and highlight the appropriate risks associated with the class of perflutren-containing microsphere contrast agents," said Mark Hibberd, M.D. PhD., Senior Medical Director, Global Medical Affairs, Lantheus Medical Imaging. "We are pleased with the collaboration between Lantheus, the echocardiography thought leaders, and the FDA which led to the revisions to the DEFINITY® label. DEFINITY® has been administered to over two million patients worldwide and remains an effective contrast imaging agent for use in patients with suboptimal echocardiograms."

The label's CONTRAINDICATIONS have been revised to the following: "Do not administer DEFINITY® to patients with known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts, hypersensitivity to perflutren. Do not administer DEFINITY® by intra-arterial injection." All other contraindications have been removed from the CONTRAINDICATIONS section of the label. The boxed WARNING and WARNINGS sections have been revised to reflect monitoring in only patients with pulmonary hypertension or unstable cardiopulmonary conditions as compared to the previous label which included language regarding monitoring in all patients.

"The decision by the FDA to revisit the changes it initially made to the DEFINITY® label last fall came after extraordinary advocacy by the global community of contrast ultrasound and echocardiography practitioners. We thank them for their efforts to further the discussion with the FDA regarding product benefit/risk assessment and appropriate use," said Don Kiepert, President and CEO, Lantheus Medical Imaging. "Lantheus Medical Imaging remains committed to providing important safety information on the use of ultrasound contrast in routine clinical practice."

More detailed information on the label change is being disseminated in a letter to healthcare professionals. Additionally, Lantheus Medical Imaging will host a webcast for healthcare providers, which is designed to provide an overview of the new Package Insert as well as provide an opportunity for customers to ask questions. For information on the webcast call 1-800-343-7851. The revised labeling for DEFINITY® and the Dear Health Care Professional letter can be found on www.lantheus.com.

About DEFINITY®

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

Lantheus recently announced the initiation of CaRES (**C**ontrast Echoc**a**rdiography **RE**gistry for **S**afety Surveillance), a multi-center Phase IV observational study that will further evaluate the safety profile of DEFINITY® in patients with suboptimal echocardiograms and provide safety information on the use of ultrasound contrast agents in routine clinical practice. The open-label, non-randomized registry will be conducted in at least 10 clinical sites in the United States and include at least 1,600 patients. The study will gather data on patient characteristics and demographics, indication for the contrast usage, safety monitoring of patients during and after DEFINITY® administration, and nature and frequency of any adverse events that may occur.

Important Safety Information about DEFINITY®

Activated DEFINITY® Vial for (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

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.**

Activated DEFINITY® should not be administered 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.

For full prescribing information, please visit www.lantheus.com.

About Lantheus Medical Imaging

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 50 years, is committed to elevating and investing in 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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[i]Source: *The Echocardiography Monthly Monitor: United States, October 2001-September 2007*, Arlington Medical Resources, Inc., Malvern, PA.

[ii]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.

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

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