

Lantheus Medical Imaging Initiates Cares Registry to Further Evaluate Definity® in Patients with Suboptimal Echocardiograms

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Phase IV Observational Study Reaffirms Company's Commitment to Patient Safety

N. Billerica, MASSACHUSETTS (May 6, 2008) – Lantheus Medical Imaging, a worldwide leader in diagnostic imaging, today announces the initiation of CaRES (Contrast Echocardiography REgistry for Safety Surveillance), a multi-center Phase IV observational study that will further evaluate the safety profile of DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension 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.

"The CaRES registry was established following discussions with the FDA to further explore the safety profile of DEFINITY as it is used in clinical practice. We believe this is the first large multi-center safety registry of its kind to be performed in the U.S.," said Mark Hibberd, M.D., Senior Medical Director, Lantheus Medical Imaging. "We expect the study to provide the physician community with important information about the safety profile of DEFINITY in patients with suboptimal non-contrast echo studies."

About Suboptimal Echocardiograms

Up to 20% of resting echocardiography studies will result in suboptimal echocardiograms.^{1,2,3} 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).^{1,2} The use of contrast in suboptimal echocardiograms may help with clinical evaluation of the patient.^{1,4}

About DEFINITY®

Since its launch in 2001, activated DEFINITY® has been administered to over two million patients.⁵ In patients with suboptimal echocardiograms, DEFINITY® enables physicians to visualize the borders of the heart more clearly.^{4,6}

Cares is also the name of Lantheus' adverse event reporting system. Call 1-800-343-7851 option 1 to report an adverse event.

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.

Warning: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or within 30 minutes following DEFINITY® administration. Assess all patients for the presence of any condition that precludes DEFINITY® administration. Monitor patients during and for 30 minutes following DEFINITY® administration, including vital sign measurements and electrocardiography in all patients and cutaneous oxygen saturation in patients at risk of hypoxemia. Always have resuscitation equipment and trained personnel readily available.

The safety and efficacy of DEFINITY® with exercise stress or pharmacologic stress testing have not been established.

Activated DEFINITY® should not be administered to patients with known or suspected cardiac shunts (right-to-left, bi-directional or transient right-to-left), unstable congestive heart failure, acute coronary syndromes (including acute myocardial infarction), serious ventricular arrhythmias (or at high risk for arrhythmias due to QT intervals prolongation), clinical significant respiratory failure, conditions that cause pulmonary hypertension (including severe emphysema or pulmonary emboli), or hypersensitivity to perflutren. Do not administer DEFINITY® by intra-arterial injection.

In post-marketing use, four patients experienced fatal cardiac arrests either during or within 30 minutes of DEFINITY® administration; one patient received DEFINITY® and underwent a cardiac stress test, two patients had severe congestive heart failure and the fourth was undergoing mechanical ventilation for respiratory failure. Other uncommon but serious reactions observed during or shortly following DEFINITY® administration included cardiac or respiratory arrest, loss of consciousness, convulsions, symptomatic arrhythmias (atrial fibrillation, supraventricular tachycardia, and ventricular tachycardia or fibrillation), hypotension, respiratory distress or cardiac ischemia. Reports of acute anaphylactoid reactions, including shock, bronchospasm, upper airway swelling, loss of consciousness, urticaria and pruritus, have occurred in patients with no prior exposure to DEFINITY®. In patients with right-to-left, bi-directional, or transient right-to-left cardiac shunts phospholipid-encapsulated microspheres can bypass the pulmonary particle-filtering mechanisms and directly enter the arterial circulation resulting in microvascular occlusion and ischemia. The safety of activated DEFINITY® at mechanical indices of >0.8 and with end-systolic triggering has not been established. Administration of activated DEFINITY® occasionally may be associated with QTc prolongation. The overall incidence of treatment-related adverse events was 8.4 percent and those reported most frequently included headache, back or renal pain, flushing, nausea, chest pain and dizziness.

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

About Lantheus Medical Imaging

Lantheus Medical Imaging, 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 TechnoLite® (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.

References

1. Mulvagh SL et al. Contrast Echocardiography: Current and future applications. *J Am Soc Echocardiogr* 2000; 13: 331-42.
2. 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.
3. Edited by Scott D. Solomon MD, *Essential Echocardiography, A Practical Handbook with DVD*. Humana Press; 2007: Chapter 5: Ventricular Systolic Function, P 113.
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5. Source: *The Echocardiography Monthly Monitor: United States, October 2001- September 2007*, Arlington Medical Resources, Inc., Malvern, PA.
6. Data on file, Lantheus Medical Imaging, Inc.

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