

Lantheus Medical Imaging Welcomes New ASE Consensus Statement on Clinical Applications of Contrast Echocardiography

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Recommendations Provide Evidence-Based Guidance for Ultrasound Contrast Use

N. BILLERICA, Mass. (November 5, 2008) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, welcomes the Consensus Statement on the Clinical Applications of Ultrasound Contrast released by the American Society of Echocardiography (ASE). Developed by members of the United States echocardiography community and published in the November issue of the *Journal of the American Society of Echocardiography*, ASE's Consensus Statement outlines when and how ultrasound contrast agents are to be used appropriately and efficiently to enhance the diagnostic capability of echocardiography.

"We applaud the American Society of Echocardiography for its leadership in addressing the effective use of contrast ultrasound by authoring the Contrast Consensus Statement guidance document for the echocardiography community. This important Consensus Statement speaks to the clinical relevance of contrast and guides clinicians towards a team-approach to care for effective contrast use," said Don Kiepert, president and CEO, Lantheus Medical Imaging. "The release of this Consensus Statement serves to validate the clinical need of ultrasound contrast use in echocardiography and reinforces the important role contrast plays in clinical diagnosis, patient management and clinical research."

ASE's Consensus Statement substantiates the established use of ultrasound contrast agents in diagnostic cardiovascular imaging in echocardiography and discusses the important role physicians, sonographers and nurses play in efficiently integrating the use of contrast agents into the echocardiography laboratory. Additionally, the document highlights the role of echocardiography contrast imaging agents in improving cardiac structural definition and outlines the clinical situations when non-enhanced imaging does not yield diagnostic information. Lantheus' echocardiography contrast agent, DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension, is specifically indicated for the use of patients with suboptimal echocardiograms to opacify the left ventricular chamber. Although the Consensus Statement also discusses, among other things, the use of contrast agents in stress echocardiography, the safety and efficacy of DEFINITY® with exercise stress or pharmacologic stress testing have not been established.

The recommendations are based on a critical review of the existing medical literature, including prospective clinical trials, and when no significant study data were available, expert consensus opinion. The Consensus Statement also thoroughly reviewed the recent labeling changes by the United States Food and Drug Administration regarding ultrasound contrast agent use and safety information.

"ASE's new recommendations provide clinicians with sound evidence-based direction and expert consensus opinion to appropriately, efficiently and effectively use ultrasound imaging contrast agents. The Consensus Statement reinforces what clinicians have seen in routine practice, namely, appropriate use of echo contrast can improve cardiac structural definition, enable clinicians to qualitatively and quantitatively assess LV function, reduce the need for subsequent testing, and enhance echocardiography laboratory efficiency," said Mark Hibberd, M.D. Ph.D., senior medical director, global medical affairs, Lantheus Medical Imaging. "ASE's recognition of contrast echocardiography as an important diagnostic tool in a broad number of clinical settings gives clinicians the direction they need to improve the standard of care for patients undergoing cardiac evaluations."

About DEFINITY®

Since its launch in 2001, activated DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension has been administered to over two million patients.¹ In patients with suboptimal echocardiograms, DEFINITY® enables physicians to visualize the borders of the heart more clearly.^{2,3}

In May 2008, Lantheus announced 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® 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 is being conducted in more than 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 DEFINITY®'s use, results of

safety monitoring of patients during and after DEFINITY® administration, and the 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, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 50 years, is committed to advancing 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.

¹ Source: *The Echocardiography Monthly Monitor: United States, October 2001-September 2007*, Arlington Medical Resources, Inc., Malvern, PA.

² 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.

³ Data on file, Lantheus Medical Imaging, Inc.

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