

CaRES Study Published in the Journal of the American Society of Echocardiography Further Demonstrates the Safety and Tolerability of Ultrasound Contrast Agent DEFINITY® in a Large and Diverse Patient Population

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Study Evaluated More Than 1,000 Patients with Wide-ranging Characteristics, Including Pre-existing Cardiopulmonary Conditions and Critical Illness, in a Routine Clinical Setting

No. BILLERICA, Mass. (July 2, 2012) – [Lantheus Medical Imaging, Inc.](#), a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced the publication of the results from the CaRES multicenter safety registry for its ultrasound imaging agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension.¹ The CaRES (Contrast Echocardiography **RE**gistry for **S**afety **S**urveillance) study, found that DEFINITY® was well-tolerated in patients of different types undergoing clinically indicated DEFINITY®-enhanced echocardiography in a broad range of typical clinical settings. The results were published in the July 2012 issue of the *Journal of the American Society of Echocardiography* (Weiss *et al.*, 2012).

“To our knowledge, the CaRES study is the first multicenter prospective registry to evaluate the safety of DEFINITY® in a large and diverse patient population and now provides physicians a measure for understanding the safety and tolerability of DEFINITY® use in a real-world, routine clinical setting,” said Mark Hibberd, M.D., Ph.D., Senior Medical Director, Global Medical Affairs, Lantheus Medical Imaging. “Across a broad range of patients with significant pre-existing cardiopulmonary conditions and suboptimal baseline echocardiograms, DEFINITY® demonstrated a consistently strong safety profile. The conclusions of this study, coupled with the recommendations for the use of contrast echocardiography by the American Society of Echocardiography², reinforce the important role of DEFINITY® in cardiac imaging.”

The prospective, open-label, non-randomized registry study was designed to assess the risk of adverse clinical events occurring within 30 minutes of DEFINITY® administration in a routine clinical setting. Among the 1,053 patients who completed the study, no deaths, life threatening events, serious adverse events or serious anaphylactoid (allergic) reactions were reported during or after DEFINITY® administration. The overall adverse event (AE) rate was 10.8%, and drug-related AE rate was 3.5 percent. Of the AEs that occurred during or after DEFINITY® administration, a substantial majority (96.5%) were mild to moderate in intensity.

The CaRES study complements another recently published study on the hemodynamic effects of DEFINITY® in patients with pulmonary hypertension.³ Published in the May 2012 issue of the *Journal of the American Society of Echocardiography* (Wei *et al.*, 2012), this prospective study evaluated 32 patients, half of whom had elevated baseline pulmonary artery systolic pressures. The study found that DEFINITY® administration did not result in any clinically meaningful changes in systemic and pulmonary artery hemodynamic measurements among patients with either normal or elevated pulmonary artery pressure. In addition, no serious or fatal adverse events occurred. Overall, DEFINITY® demonstrated a positive safety profile and was well-tolerated.

Both the CaRES study and the pulmonary hypertension study were developed in conjunction with the U.S. Food and Drug Administration (FDA) in 2008 as part of a risk assessment program for perflutren-based ultrasound contrast agents, such as DEFINITY®. In October 2011, the FDA approved several revisions to the DEFINITY® prescribing information, including the removal of mandatory physiologic monitoring requirements for patients with pulmonary hypertension or unstable cardiopulmonary conditions. Data from both the CaRES and pulmonary hypertension studies were included in the updated DEFINITY® labeling.⁴ “The CaRES study builds on a large and growing body of peer-reviewed literature and a decade of real-world experience which support a well-characterized and favorable benefit-risk profile for DEFINITY®,” added Dana Washburn, M.D., Chief Medical Officer at Lantheus Medical Imaging.

About the CaRES Study

The CaRES study enrolled a total of 1,060 patients at 15 clinical sites in the United States. Of these enrollees, 1,053 received at least one dose of DEFINITY® and completed the study. Safety monitoring including vital sign measurements, continuous electrocardiographic monitoring, and continuous oxygen saturation was conducted before and, at regular intervals for 30 minutes, after DEFINITY® administration. Adverse events were assessed at 30 minutes after receiving DEFINITY® and patients were

contacted by telephone 24 ± 4 hours later to record any subsequent adverse events.

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.^{5,6} The use of contrast in suboptimal echocardiograms may help with clinical evaluation of the patient.^{5,8}

About DEFINITY®

DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension is an ultrasound contrast agent for use in patients with suboptimal echocardiograms (see Indications and Important Safety Information below and find full Prescribing Information at <http://www.definityimaging.com>).⁴ Since its launch in 2001, activated DEFINITY® has been administered to more than 3.5 million patients.⁹

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.

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 uncommonly during or following perflutren-containing microsphere administration [See WARNINGS AND PRECAUTIONS (5.1)]. Most serious reactions occur within 30 minutes of administration.

- Assess all patients for the presence of any condition that precludes DEFINITY® administration [See CONTRAINDICATIONS (4)].
- 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 (6)]. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions [See Postmarketing Experience (6.2)]. It is not always possible to reliably establish a causal relationship to drug exposure due to the presence of underlying cardiopulmonary disease.

Please see full Prescribing Information, including boxed **WARNING** regarding serious cardiopulmonary reactions, on www.definityimaging.com.

About Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The Company's proven success in the field of diagnostic imaging 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, an ultrasound contrast agent for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border, 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, TechnoLite® (Technetium Tc99m Generator), Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride TI 201 Injection). Lantheus has approximately 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to risks and uncertainties that may be described from time to time in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

References

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