Lantheus Medical Imaging Announces Labeling Changes for DEFINITY®

October 28, 2011 1:46 PM ET

Revised Label Modifies Patient Monitoring and Observation Requirements
Following DEFINITY® Administration

No. BILLERICA, Mass. (October 27, 2011) – Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced important changes to the U.S. product label for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension. DEFINITY® 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[1].

After a review of Lantheus' 2010 application for proposed label changes submitted to the U.S. Food and Drug Administration (FDA), the following revisions have been made to the Prescribing Information for DEFINITY®:

- Removal of the statement from the boxed **WARNING***: "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."* Similar language was also removed from the WARNING section of the label.
- Addition of the statement to the boxed **WARNING**: *"Most serious reactions occur within 30 minutes of administration,"* which is consistent with the current information in the WARNING section.
- Removal of the statement from the product Indications and Usage section of the label: *"The safety and efficacy of DEFINITY® with exercise stress or pharmacologic stress testing have not been established."*
- Addition of the further qualifier in the statement in the WARNING section: "Serious cardiopulmonary reactions, including fatalities, have occurred '*uncommonly*' during or following perflutren-containing microsphere administration."
- Inclusion of summary data from post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry in the Post-Marketing Experience section and from post-approval pulmonary hypertension study in the Clinical Trials Experience section.

"We are pleased the FDA has approved the revisions to the DEFINITY® prescribing information," said Don Kiepert, President and Chief Executive Officer, Lantheus Medical Imaging. "DEFINITY® is an important diagnostic tool that can provide critical patient information to help physicians make better informed patient management decisions. We believe the changes to the label more accurately reflect the benefit-risk profile and tolerability of DEFINITY®, which has been well established in real-world use, clinical studies and peer-reviewed literature for more than a decade."

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 and find full Prescribing Information at http://www.definityimaging.com)1. Since its launch in 2001, activated DEFINITY® has been administered to more than three million patients[2].

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
See full prescribing information for complete boxed warning

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration (5.1). Most serious reactions occur within 30 minutes of administration.

- Assess all patients for the presence of any condition that precludes DEFINITY® administration (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). The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (See Postmarketing Experience). 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, 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 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.

1. DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2011