Lantheus Medical Imaging Presents Promising Results of Latest Safety Studies

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No. BILLERICA, Mass. (May 3, 2011) – Lantheus Medical Imaging, a worldwide leader in diagnostic medical imaging, completed a successful meeting with the U.S. Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee and Risk Management Advisory Committee, which convened on May 2, 2011 to review safety data of ultrasound contrast agents from three manufacturers. The meeting was intended to provide an interim update on post-marketing safety studies and pharmacovigilance activities since the last advisory committee meeting in 2008. Lantheus Medical Imaging presented safety data for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension.

"DEFINITY® is an important diagnostic cardiovascular imaging tool with a well-characterized safety profile," said Don Kiepert, President and Chief Executive Officer, Lantheus Medical Imaging. "We were pleased to have the opportunity to present our data and report that after almost a decade of real-world use, the clinical value and safety profile of DEFINITY® is well established in clinical trials, peer-reviewed literature, and among physicians and echocardiographers."

Data from two post-marketing studies was presented to the advisory committees. The first study is a Phase 4 observational registry study featuring 1,053 patients[1], a majority of whom had underlying cardiac and/or pulmonary disease. Investigators did not report any serious adverse events or any fatal events and found only 3.5 percent[2]of patients reporting minor, transient treatment-related adverse events consistent with the DEFINITY® labeling. In addition, during and for 30 minutes after DEFINITY® administration, patients did not experience clinically significant changes in vital signs, electrocardiograms or oxygen saturation levels.

The second study evaluated 32 patients, half of whom had elevated pulmonary artery systolic pressure. **Investigators followed the label's monitoring guidelines and found** DEFINITY® administration did not result in any clinically or statistically significant changes in systemic and pulmonary artery hemodynamic measurements in patients with normal or elevated pulmonary artery pressure. In addition, no serious adverse events, including fatal events, occurred. Overall, DEFINITY® demonstrated a positive safety profile and was well tolerated.

The Company also presented results from a retrospective study examining 48-hour mortality rates of critically ill, hospitalized patients undergoing contrast versus noncontrast echocardiography. The study evaluated a total of 31,596 patient cases[3] with 23 co-morbidities[4], half of whom received DEFINITY® echocardiography, while the other half received noncontrast echocardiography. Results showed the DEFINITY® group had a 32 percent[1] lower mortality than the noncontrast group. Also, patients with serious co-morbidities, such as acute myocardial infarction, mechanical ventilation, congestive heart failure, cardiogenic shock and pulmonary hypertension, had significantly lower mortality rates in the DEFINITY® group versus the noncontrast group.

At yesterday's advisory committee meeting, Lantheus also presented three years of surveillance data, which showed the stable adverse event rate and that the DEFINITY® safety profile remained unchanged.

"The goal of our presentation was to reinforce that DEFINITY® is well tolerated among high-risk patients and has a stable, well-characterized safety profile, said Mark G. Hibberd, M.D., Ph.D., Senior Medical Director, Global Medical Affairs and Pharmacovigilance, Lantheus Medical Imaging. "During the three years since the last FDA advisory committee meeting, there have been no significant changes to the DEFINITY® safety profile and the rate of adverse events has remained approximately the same. Lantheus remains committed to patient safety and looks forward to working with the FDA regarding appropriate labeling for DEFINITY®."

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)[6].

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

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 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.**

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 pulmonary hypertension or unstable cardiopulmonary conditions. It is not always possible to reliably establish a causal relationship to drug exposure due to the presence of underlying cardiopulmonary disease.

About Lantheus Medical Imaging, Inc.
Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for more than 50 years, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The company's proven success in discovering, developing and marketing innovative medical imaging agents 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 more than 650 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. For more information, visit www.lantheus.com.

1. Lantheus Briefing Document. Page 19, Section 4.1.1.1

2. Lantheus Briefing Document. Page 27, Section 4.1.1.4

3. Lantheus Briefing Document. Page 34, Section 4.1.3.1

4. Lantheus Briefing Document. Page 34, Section 4.1.3.1

5. Lantheus Briefing Document. Page 37, Section 4.1.3.2

6. DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2009.