Lantheus Medical Imaging, Inc. Commends Safety Labeling Changes Announced by U.S. Food and Drug Administration for Gadolinium-Based Contrast Agents

September 10, 2010 4:13 PM ET

-- No Substantial Changes Made to ABLAVAR® (Gadofosveset Trisodium) Labeling --

N. BILLERICA, Mass. (September 10, 2010) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medical imaging, supports the U.S. Food and Drug Administration's (FDA) announcement requiring safety-related label changes for all gadolinium-based contrast agents to highlight the rare and potentially fatal condition known as nephrogenic systemic fibrosis (NSF). Of the seven gadolinium-based contrast agents currently approved for use in the United States, three of them are now being required by FDA to include certain new contraindications relating to severe kidney disease. No substantial changes will be required by FDA to the ABLAVAR® (gadofosveset trisodium) prescribing information. ABLAVAR® is a unique, single, low dose injectable magnetic resonance angiography (MRA) blood pool imaging agent for use to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease (PVD). ABLAVAR® is the first and only imaging agent with an FDA-approved indication for use with MRA.

"We support the FDA for taking action to ensure the safe and appropriate use of gadolinium-based contrast agents, and we agree with the changes put forth by the FDA for ABLAVAR®," said Mark Hibberd, M.D., Ph.D., Senior Medical Director, Lantheus Medical Imaging, Inc. "The revised language provides clearer guidance to healthcare professionals about the risk of gadolinium-based contrast agent-associated NSF in patients who are renally impaired. ABLAVAR® is uniquely designed for vascular imaging and has a strong safety profile. To date, there have been no reported incidents of NSF with ABLAVAR®.[1] We remain committed to working with the FDA to provide the most current and accurate safety information for the product."

About ABLAVAR® (gadofosveset trisodium)
ABLAVAR® is the first and only blood pool contrast agent approved for magnetic resonance angiography to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease. The albumin-binding properties of ABLAVAR®make it uniquely designed for vascular imaging allowing multiple images to be obtained using a single, low dose injection. ABLAVAR®is clinically proven to produce high resolution MRA images, combining both dynamic (first pass) and steady state imaging, resulting in diagnostic accuracy comparable to conventional X-ray angiography[2,3], the current standard of care for diagnosing vascular disease such as AIOD. Gadofosveset trisodium has been used in nearly 90,000 patients to date.1 Lantheus acquired exclusive rights for ABLAVAR® in the United States, Canada and Australia in April 2009, and the product was launched in the United States in January 2010. The company announced the purchase of the balance of the worldwide rights for the product in July 2010.

Indications:
ABLAVAR®is indicated for use as a contrast agent in magnetic resonance angiography (MRA) to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease.

Contraindications:
History of a prior allergic reaction to a gadolinium-based contrast agent.

Important Safety Information About ABLAVAR®:

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents increase the risk of nephrogenic systemic fibrosis (NSF) in patients with:

- **acute or chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73m^2), or**
- **acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period.**

In these patients, avoid use of gadolinium-based contrast agents unless the diagnostic information is essential and not available with non-contrast

enhanced magnetic resonance imaging (MRI). NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle, and internal organs. Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests. When administering a gadolinium-based contrast agent, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any re-administration.

ABLAVAR®Injection: As with other contrast media: the possibility of serious or life-threatening anaphylactic or anaphylactoid reactions, including cardiovascular, respiratory and/or cutaneous manifestations, should always be considered. As with other paramagnetic contrast agents, caution should be exercised in patients with renal insufficiency due to the possibility of further deterioration in renal function.

In clinical trials, a small increase (2.8 msec) in the average change from baseline in QTc was observed at 45 minutes. These QTc prolongations were not associated with arrhythmias or symptoms. Caution should be used in patients at high risk for arrhythmias due to baseline QTc prolongation.

Have emergency resuscitative equipment available prior to and during ABLAVAR® administration.

Please see full Prescribing Information, including boxed **WARNING** regarding Nephrogenic Systemic Fibrosis (NSF), at www.ablavar.com.

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 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. For more information, visit www.lantheus.com.

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1. Data on file, Lantheus Medical Imaging, Inc.

2. Goyen, M, Edelman, M, Perreault, P, et al. MR Angiography of Aortoiliac Occlusive Disease: A Phase III Study of the Safety and Effectiveness of the Blood-Pool Contrast Agent MS-325. *Radiology*. 2005; 236(3):825-833.

3. Rapp, JH, Wolff, SD, Quinn, SF, et al. Aortoiliac Occlusive Disease in Patients with Known or Suspected Peripheral Vascular Disease: Safety and Efficacy of Gadofosveset-Enhanced Angiography – Multicenter Comparative Phase III Study. *Radiology*. 2005; 236(1):71-78.