

## **Lantheus Medical Imaging, Inc. Launches ABLAVAR™ (Gadofosveset Trisodium), a New Diagnostic Magnetic Resonance Angiography Agent**

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ABLAVAR™ is the First and Only Contrast Imaging Agent Approved for Use With  
Magnetic Resonance Angiography (MRA) in the United States

**N. BILLERICA, Mass. (January 20, 2010)** – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced the launch of ABLAVAR™ (gadofosveset trisodium), a unique, injectable MRA imaging agent used to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease (PVD). ABLAVAR™ is the first and only contrast imaging agent approved in the United States for use with a magnetic resonance angiography (MRA) indication to evaluate AIOD. AIOD is a type of PVD that occurs when arteries, which carry blood from the heart to the lower limbs, become narrowed or blocked. This lack of blood supply can result in pain, infection and even loss of limbs<sup>1</sup>.

In Phase 3 clinical studies, ABLAVAR™ demonstrated statistically greater sensitivity (detecting disease when present) compared with non-contrast MRA<sup>2</sup>. These studies, which supported the U.S. Food and Drug Administration (FDA) approval of ABLAVAR™, show that MRA images using ABLAVAR™ provided diagnostic accuracy comparable to conventional X-ray angiography,<sup>3,4</sup> an invasive procedure which involves insertion of a catheter into the arteries in the upper thigh (groin area) or arm<sup>5</sup>.

“ABLAVAR™ provides distinct advantages over X-ray angiography, the current standard of care in diagnosing AIOD,” said Mark G. Hibberd, M.D., Ph.D., Senior Medical Director, Global Medical Affairs, Lantheus Medical Imaging, Inc.

“ABLAVAR™ provides high resolution images comparable to conventional X-ray angiography (the current gold standard), which offers radiologists a clear, enhanced visualization of patients’ arteries. However, ABLAVAR™ is given in a single, low dose injection, does not require catheter insertion into a patient’s arteries, and does not expose patients to ionizing radiation, all of which are tangible benefits to patients.”

“ABLAVAR™ may provide clinicians performing vascular imaging with more comprehensive, three-dimensional diagnostic information to improve patient treatment decisions and care,” added E. Kent Yucel, M.D., FACR, Chairman of Radiology, Tufts Medical Center. “ABLAVAR™, as the first FDA-approved contrast agent for an MRA indication, is a welcome addition to the currently available options for diagnosing AIOD in patients with known or suspected peripheral vascular disease.”

“We are pleased to realize our goal of launching ABLAVAR™, as it can provide patients and clinicians with the first and only product that is approved by the FDA for use with an MRA indication and is specifically indicated for detecting aortoiliac occlusive disease,” said Don Kiepert, President and CEO of Lantheus Medical Imaging, Inc. “With the introduction of this first-in-class imaging agent, we extend our presence into the radiology and peripheral vascular disease markets, and expand our portfolio of diagnostic imaging agents to now include MRI as well as SPECT, PET and echocardiography imaging modalities.”

### **About Magnetic Resonance Angiography**

Magnetic resonance angiography (MRA) is a specific type of magnetic resonance imaging (MRI) procedure that provides pictures of blood vessels. MRA can show the blockage of the flow of blood to areas of the body such as the brain, kidneys and legs. In the United States, an estimated 3.6 million MRA procedures are performed each year<sup>6</sup>.

### **About Aortoiliac Occlusive Disease**

Aortoiliac occlusive disease (AIOD), a type of peripheral vascular disease (PVD), occurs when the aorta and iliac arteries become narrowed or blocked. Arteries are normally smooth and unobstructed on the inside, but with age, plaque can build up in the walls of arteries and cause them to narrow and stiffen. Atherosclerosis, or hardening of the arteries, causes most cases of AIOD. Those affected with AIOD may not receive the blood and oxygen they need throughout their legs, causing pain, sores or gangrene, which can result in the loss of a limb<sup>1</sup>. PVD, also known as peripheral arterial disease<sup>7</sup>, refers to diseases of blood vessels outside the heart and brain. PVD of the lower extremities affects eight to 12 million people in the United States<sup>8</sup>. Risk factors for AIOD are similar to those associated with cardiovascular disease including smoking, obesity, diabetes, high blood pressure and high cholesterol<sup>8</sup>.

### **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 patients 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<sup>3,4</sup>, the current standard of care for diagnosing vascular disease such as AIOD. ABLAVAR™ is approved in 37 countries outside the United States and has been used in nearly 90,000 patients to date<sup>2</sup>. Lantheus owns the rights to ABLAVAR™ in the United States, Canada and Australia.

**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<sup>2</sup>), 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](http://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 treatment of human disease. The company's proven success in discovering, developing and marketing innovative medical imaging agents provides a solid platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. The company is home to leading cardiac 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). The company is also now home to ABLAVAR™ (gadofosveset trisodium), a first-in-class blood pool contrast agent for magnetic resonance angiography. 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](http://www.lantheus.com).

<sup>1</sup> Vascular Web. Society for Vascular Surgery. Aortoiliac Occlusive Disease. [http://www.vascularweb.org/patients/NorthPoint/Aortoiliac\\_Occlusive\\_Disease.html](http://www.vascularweb.org/patients/NorthPoint/Aortoiliac_Occlusive_Disease.html). Assessed on October 26, 2009.

<sup>2</sup> Data on file, Lantheus Medical Imaging, Inc.

<sup>3</sup> 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.

<sup>4</sup> 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 MR Angiography – Multicenter Comparative Phase III Study. *Radiology*. 2005; 236(1):71-78.

<sup>5</sup> American Heart Association. What is Coronary Angiography? <http://www.americanheart.org/presenter.jhtml?identifier=11222>. Assessed on October 26, 2009.

<sup>6</sup> The Imaging Market Guide (US Edition 2009), Arlington Medical Resources, Inc. Malvern, PA.

<sup>7</sup> National Heart, Lung, and Blood Institute. National Institutes of Health. Other Names for Peripheral Arterial Disease. [http://www.nhlbi.nih.gov/health/dci/Diseases/pad/pad\\_onames.html](http://www.nhlbi.nih.gov/health/dci/Diseases/pad/pad_onames.html). Assessed March 30, 2009.

<sup>8</sup> National Heart, Lung, and Blood Institute. National Institutes of Health. Who Is At Risk for Peripheral Arterial Disease? [http://www.nhlbi.nih.gov/health/dci/Diseases/pad/pad\\_risk.html](http://www.nhlbi.nih.gov/health/dci/Diseases/pad/pad_risk.html). Assessed March 30, 2009.