

## **Data Featuring Gadofosveset Trisodium, the First and Only MRA Blood Pool Agent Approved in the U.S. Presented at MRA-Club 09: 21st Annual International Conference on Magnetic Resonance Angiography**

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### ***ABLAVAR™ Designated as Brand Name for Gadofosveset Trisodium***

N.BILLERICA, Mass. (October 8, 2009) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced that two oral presentations featuring gadofosveset trisodium, the first and only FDA approved blood pool contrast agent for magnetic resonance angiography (MRA), were presented at MRA-Club 09: The 21st Annual International Conference on Magnetic Resonance Angiography. The company also announced today that ABLAVAR™ has been chosen as the brand name for gadofosveset trisodium.

The first presentation entitled, “An Update on the Clinical Experience with Gadofosveset,” was presented by Mark G. Hibberd, M.D., Ph.D., Senior Medical Director, Global Medical Affairs, Lantheus Medical Imaging, Inc. This presentation included the review of safety and efficacy data from the clinical use of ABLAVAR™ in Europe and Canada (over three years of marketing data) and from the US-FDA approval of MS-325 in December 2008. The establishment of a new clinical registry in the United States was also announced. The presentation confirmed that ABLAVAR™ has not been associated with nephrogenic systemic fibrosis (NSF) to date.

The second oral presentation, “A Re-analysis of MS-325 (Gadofosveset Trisodium) Clinical Trial Data in Support of U.S. FDA Approval,” was given by Edward Parsons, Ph.D., formerly of EPIX Pharmaceuticals, Inc. and currently a consultant to Lantheus Medical Imaging, Inc. This presentation, which reported a blinded, independent re-read of images from previous Phase 3 studies, found that ABLAVAR™ demonstrated statistically greater sensitivity (detecting disease when present) compared with non-contrast MRA<sup>1</sup>. The study also showed that ABLAVAR™ had non-inferior specificity (excluding disease when not present) with non-contrast MRA<sup>1</sup>. Thus ABLAVAR™ MRA images provided diagnostic accuracy superior to non-contrast MRA and comparable to traditional X-ray angiography<sup>1</sup>.”

“The data presented at the recent MRA Club meeting supports the safety and efficacy of ABLAVAR™, a first-in-class imaging agent we are planning to introduce to the U.S. market in the coming months,” said Dr. Hibberd. “We are confident that ABLAVAR™ will make it possible for physicians to detect aortoiliac occlusive disease less invasively than with the current gold standard – X-ray angiography – and, importantly, without exposing the patient to ionizing radiation. Furthermore, ABLAVAR™ is used in a single low dose which allows both first pass and high resolution blood pool imaging.”

In April 2009, Lantheus Medical Imaging, Inc. acquired the U.S., Canadian, and Australian rights to gadofosveset trisodium (formerly known as MS-325) from EPIX Pharmaceuticals, Inc. The product is approved in 38 countries worldwide and has been used in more than 60,000 patients in Europe<sup>2</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 unique albumin-binding properties of ABLAVAR™ make it ideal for vascular imaging allowing multiple images to be obtained using a single, low dose injection. ABLAVAR™ enables the visualization of both arterial and venous blood vessels. 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 X-ray angiography, the current standard of care for diagnosing vascular disease such as AIOD<sup>3,4</sup>.

#### **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).

### **About Lantheus Medical Imaging, Inc.**

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 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 TechnoLite® (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 nearly 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> Data on file.

<sup>2</sup> Period Safety Update Report (PSUR) on file with the European Medicines Agency (EMA). Data was supplied through October 2008.

<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.