



Lantheus Announces Presentation of New Patient Outcomes Data for DEFINITY® at the American Society of Echocardiography 2019 Annual Scientific Sessions

Jun 24, 2019

Findings Show Improved Clinical Management and Decreased Length of Stay in Intensive Care Unit Patients Receiving DEFINITY-Enhanced Echocardiography Versus Non-Contrast Echocardiography Patients

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jun. 24, 2019-- [Lantheus Holdings, Inc.](#) (NASDAQ: LNTN), the parent company of [Lantheus Medical Imaging, Inc.](#) ("LMI"), a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products, today announced new clinical outcomes data for [DEFINITY® Vial for \(Perflutren Lipid Microsphere\) Injectable Suspension](#) demonstrating the positive impact of contrast echocardiography with DEFINITY in intensive care unit (ICU) patients as compared to ICU patients who received echocardiography without contrast. The data will be presented during a poster session today at 9:00 a.m.-4:00 p.m. PT at the American Society of Echocardiography (ASE 2019) Annual Scientific Sessions. DEFINITY is a cardiovascular ultrasound contrast agent currently 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

The study findings show that DEFINITY-enhanced echocardiography in the ICU setting, in comparison with non-contrast transthoracic echocardiography (TTE), is associated with lower rates of subsequent TTE and transesophageal echocardiography (TEE) during the index hospitalization, shorter ICU length of stay, and significant changes in use of vasoactive medications.

"These clinical outcomes data are important and reveal that use of contrast echocardiography with DEFINITY is associated with reduced subsequent cardiac ultrasound testing and reduced length of stay for ICU patients," said Michael L. Main, M.D., lead investigator and co-executive medical director of Saint Luke's Mid America Heart Institute in Kansas City. "Patients in critical care settings are often difficult to image due to their medical conditions, and as a result, suboptimal images are obtained up to 25 percent of the time, impacting diagnostic accuracy and confidence. The use of contrast enhanced echocardiography in obtaining accurate and interpretable images is critical in influencing patient diagnosis, treatment, and clinical outcomes."

The Premier Healthcare Database was analyzed to identify ICU patients receiving DEFINITY as compared to no use of contrast during the initial rest TTE in ICU patients. Primary outcomes of interest were subsequent TTE and TEE during the index hospitalization and ICU length of stay. The data results from the retrospective observational study, with patient data captured between January 1, 2009 and September 30, 2015, showed a total of 1,538,864 patients from 773 hospitals were identified as undergoing resting TTE in the ICU with DEFINITY in 51,141 (3.3%) patients and no contrast agent use in 1,487,723 (96.7%) patients. After adjusting for patient, clinical, and hospital characteristics, an adjusted analysis for subsequent TTE and TEE showed that during the index hospitalization, patients in the DEFINITY cohort were less likely to undergo a subsequent TTE or TEE as compared to those in the no contrast cohort (odds ratio=0.704 for TTE, odds ratio=0.841 for TEE; p<0.0001 for both). Adjusted mean ICU length of stay for the DEFINITY cohort was approximately 10% shorter than that of the no contrast cohort (4.15 vs. 4.59 days, p<0.0001). Compared to the no contrast cohort, patients in the DEFINITY cohort were more likely to start use of parenteral inotrope (3.8% vs. 2.4%), end use of parenteral inotrope (0.6% vs. 0.3%), start use of parenteral pressor (12.8% vs. 11.6%) and end use of parenteral pressor (4.3% vs. 3.2%) on the day of, or one day after the index TTE (all p<0.0001).

"These data findings support the use of contrast echocardiography with DEFINITY in improving patient outcomes in a critical care environment and add to the robust clinical evidence for DEFINITY," said Mary Anne Heino, president and chief executive officer of Lantheus Medical Imaging. "Echocardiography is widely considered to be a non-invasive, highly informative, radiation-free, portable and cost-effective cardiac diagnostic tool that allows clinicians to image critically ill patients at their bedside. DEFINITY-enhanced echocardiography improves visualization of suboptimal images to provide valuable real-time cardiac structural and functional information to increase diagnostic accuracy and confidence, reducing the need for additional diagnostic procedures."

About Echocardiography

Echocardiography is a powerful and reliable modality for diagnosing and monitoring cardiac patients. In January 2019, a group of leading medical societies including American College of Cardiology, American Society of Echocardiography, American Heart Association, and American Society of Nuclear Cardiology, published the *2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease*. The document outlines the range of modalities that may be reasonable for specific indications. The societies determined that the use of echocardiography is considered "appropriate" for the evaluation of a number of cardiac conditions, including the use of TTE for the initial cardiac evaluation of a known systemic, congenital, or acquired disease that could be associated with structural heart disease.² The committee also stated that the modalities are not to be considered in a rank order and may be used relative to individual patient circumstances

and the balance of risk versus benefit.³

About DEFINITY®

[DEFINITY Vial for \(Perflutren Lipid Microsphere\) Injectable Suspension](#) is an ultrasound contrast agent for use in patients with suboptimal echocardiograms (see Indications and Important Safety Information below and find full Prescribing Information at www.definityimaging.com).¹ DEFINITY is engineered to produce small and consistently sized durable microbubbles to fully evaluate the left ventricle.¹ DEFINITY® has extensive safety experience and a consistent safety profile.⁴ Since its launch in 2001, more than 11 million echo studies have been performed with DEFINITY® and it is the most prescribed contrast agent in the U.S.⁵

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 hypersensitivity to perflutren.

IMPORTANT SAFETY INFORMATION

WARNING: Serious Cardiopulmonary Reactions

- Assess all patients for the presence of any condition that precludes DEFINITY® administration [see *Contraindications (4)*].
- Always have resuscitation equipment and trained personnel readily available.

In post marketing use, rare but serious cardiopulmonary or hypersensitivity reactions have been reported during or shortly following perflutren-containing microsphere administration [see *Adverse Reactions (6)*]. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions [see *Adverse Reactions (6.2)*]. 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 Holdings and Lantheus Medical Imaging, Inc.

[Lantheus Holdings, Inc.](#) is the parent company of [LMI](#), a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. LMI provides a broad portfolio of products, including the echocardiography contrast agent [DEFINITY® Vial for \(Perflutren Lipid Microsphere\) Injectable Suspension](#) and [TechneLite® \(Technetium Tc99m Generator\)](#), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures. The Company is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

¹ DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2017.

^{2,3} 2019 *Appropriate Use Criteria for Multimodality Imaging in Nonvalvular Heart Disease*, D. Mukherjee, M.D., FACC, January 7, 2019, www.acc.org

⁴ Data on file, Lantheus Medical Imaging Inc.

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