Lantheus Medical Imaging Announces FDA Approval of DEFINITY® Label Update

Feb 2, 2017

Label Revision Removes Cardiac Shunt Contraindication

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Feb. 2, 2017-- Lantheus Medical Imaging, Inc. ("Lantheus") today announced U.S. Food and Drug Administration (FDA) approval of an important label update for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension which removes the contraindication statement related to use in patients with a known or suspected cardiac shunt from the U.S. Prescribing Information. DEFINITY 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.[1]

A cardiac shunt is a pattern of blood flow in the heart that deviates from the normal path of the circulatory system, which may present in 10 to 35 percent of patients.[2] These patients were previously excluded from receiving a valuable echo contrast study of the left ventricle. The FDA's decision to remove the contraindication concerning known or suspected cardiac shunts was based on Lantheus' submission referencing several publications and data supporting the safety of echocardiography contrast products in patients with cardiac shunts. Information concerning administration in patients with a cardiac shunt appears in the Warnings section of the DEFINITY Prescribing Information.

"The label change implemented by FDA is reflective of both the extensive data on contrast agents and the well characterized and stable safety profile of DEFINITY, which has been used to perform more than seven million echocardiography studies," said Cesare Orlandi, Chief Medical Officer at Lantheus. "The removal of the cardiac shunt contraindication is expected to provide patients who could benefit from this important diagnostic tool with greater access to DEFINITY when undergoing cardiac ultrasound imaging."

Neil Weissman, M.D., President of MedStar Health Research Institute (Washington, DC), Professor of Medicine at Georgetown University and Past President of the American Society of Echocardiography commented, "The echocardiography medical and scientific community has long demonstrated the safety of echocardiographic contrast agents through published clinical studies which has supported the removal of the contraindication for DEFINITY in patients with cardiac shunts. This is particularly noteworthy as DEFINITY is the most widely used echocardiography agent in the U.S. with published data supporting its safety profile across multiple care settings and across gender and race in adults, including those age 65 and older."

Dr. Weissman continued, "This is an important step toward broader acceptance and appropriate use of echo contrast agents, which can safely and cost effectively provide critical information to help clinicians accurately diagnose and manage patients to achieve better outcomes."

About Suboptimal Echocardiograms
Up to 20 percent of all resting echocardiography studies and up to 30 percent of those conducted in critical care patients can result in suboptimal echocardiograms.[3-6] A suboptimal image is one in which two or more contiguous left ventricular segments in any of the three apical views cannot be visualized.[3,4,7] The use of contrast in suboptimal echocardiograms may help with clinical evaluation of the patient.[4,8]

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.[9] Since its launch in 2001, more than seven million echo studies have been performed with DEFINITY and it is the most prescribed contrast agent in the U.S.[10]

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

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration *[see Warnings and Precautions (5.1)]*. Most serious reactions occur within 30 minutes of administration.

- 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 Medical Imaging, Inc.
Lantheus Medical Imaging, Inc., a subsidiary of Lantheus Holdings, Inc. (NASDAQ: LNTH), is a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. Lantheus provides a broad portfolio of products, which are primarily used for the diagnosis of cardiovascular diseases. Lantheus' key products include the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; TechneLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; and Xenon (Xenon Xe 133 Gas), an inhaled radiopharmaceutical imaging agent used to evaluate pulmonary function and for imaging the lungs. Lantheus is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to risks and uncertainties that may be described from time to time in Lantheus Holdings, Inc. filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus Holdings, Inc. undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

[1] DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2017.
[2] Parker JM, et al, Safety of ultrasound contrast agents in patients with known or suspected cardiac shunts. Am J Cardiol. 2013; 112:1039-1045.
[3] Waggoner AD, et al, Guidelines for the cardiac sonographer in the performance of contrast echocardiography. J Am Soc Echocardiogr. 2001: 417-420.
[4] Mulvagh S et al. *J Am Soc Echocardiogr*. 2008;21(11):1179-1201
[5] Edited by Scott d. Solomon, MD, Essential Echocardiography, A Practical handbook with DVD. Humana Press; 2007 Chapter Ventricular Systolic function, P113.
[6] Kurt M, Shaikh, et al. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospective cohort. *J Am Coll Cardiol.* 2009;53(9):802-810.
[7] IAC Standards and Guidelines for Adult Echocardiography Accreditation http://www.intersocietal.org/echo/standards/IACAdultEchocardiographyStandards2014.pdf
[8] Kitzman DW et al. Efficacy and safety of the novel ultrasound contrast agent perflutren (Definity) in patients with suboptimal baseline left ventricular echocardiographic images. *Am J Cardiol*. 2000; 86: 669-674
[9] Data on file, Lantheus Medical Imaging, Inc.
[10] ©2016 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170202005351/en/

Source: Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc.
Media
Meara Murphy, 978-671-8508
Director, Investor Relations & Corporate Communications
or
Investors
Gary Santo, 978-671-8960
Head of Capital Markets & Investor Relations