

Lantheus Medical Imaging Announces FDA Approval of Jubilant HollisterStier

February 11, 2013 5:21 PM ET

Important Advance in Supply Chain Diversification Strategy to Ensure Consistent, Reliable Supply of Key Products

No. BILLERICA, Mass. (February 11, 2013) – [Lantheus Medical Imaging, Inc.](#), a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced that the U.S. Food and Drug Administration (FDA) has granted approval of a Supplemental New Drug Application (sNDA) that allows Jubilant HollisterStier (JHS) to be a new manufacturing site for its ultrasound imaging agent DEFINITY[®] Vial for (Perflutren Liquid Microsphere) Injectable Suspension.¹ DEFINITY[®] is an ultrasound contrast agent 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

“FDA approval of JHS as a new manufacturer for DEFINITY[®] is a major step forward in providing consistent and reliable supply to our customers,” said Jeff Bailey, Lantheus President and Chief Executive Officer. “Supply chain diversification is a significant priority for the Company as we work to ensure long-term product availability to meet market demand. We remain dedicated to providing the highest quality products to our customers and the patients they serve.”

Currently, DEFINITY[®] is manufactured by Ben Venue Laboratories (BVL) in Bedford, OH. In August 2011, BVL announced that it will exit the contract manufacturing services business over the next several years. In February 2012, Lantheus entered into a manufacturing and supply agreement with JHS for the manufacture of DEFINITY[®]. Additionally, the Company entered into similar agreements with JHS in May 2012 for the manufacture and supply of Cardiolute[®] and Neurolite[®], which are also currently manufactured by BVL. JHS will become the Company’s lead supplier of DEFINITY[®], as well as Cardiolute[®] and Neurolite[®], as BVL transitions out of the contract manufacturing services business. Lantheus is currently working to secure additional alternative suppliers for its key products as part of its ongoing supply chain diversification strategy.

About DEFINITY[®]

DEFINITY[®] Vial for (Perflutren Lipid Microsphere) Injectable Suspension is an ultrasound contrast agent for use in patients with suboptimal echocardiograms (see Indications below and find full Prescribing Information at <http://www.definityimaging.com>).¹ Since its launch in 2001, activated DEFINITY[®] has been administered to more than 3.9 million patients.²

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 right-to-left, bi-directional or transient right-to-left cardiac shunts, by intra-arterial injection, or to patients with known 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 anaphylactoid 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 Postmarketing Experience (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 global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The Company's proven success in the field of diagnostic imaging 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, an ultrasound contrast agent for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border, Technelite® (Technetium Tc 99m Generator), Cardiolite® (Kit for the Preparation of Technetium Tc 99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride Tl 201 Injection). Lantheus has approximately 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. 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 our 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. The Company 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.

References

1. DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2011.
2. ©AMR Echocardiography Monthly Monitor Market Guide – US (2001-2012). AMR/Arlington Medical Resources, LLC. All right reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.