

#### FOR IMMEDIATE RELEASE

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# Lantheus Medical Imaging Announces FDA Approval of Jubilant HollisterStier as a New Manufacturing Site for NEUROLITE®

Approval Marks Important Step in Ensuring Continued Supply of Brain Imaging Agent

No. BILLERICA, Mass. (January 29, 2015) – Lantheus Medical Imaging, Inc. (Lantheus), a global leader in developing, manufacturing, selling 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 proprietary brain perfusion imaging agent NEUROLITE® (Kit of the Preparation of Technetium Tc99m Bicisate for Injection). NEUROLITE, a technetium-based single-photon emission computed tomography (SPECT) radiopharmaceutical agent, provides healthcare providers with critical neurological information for patients.

"FDA approval of JHS as a new manufacturer for NEUROLITE is a major step forward in ensuring that there is long-term, sufficient supply of NEUROLITE available to meet market demand for brain perfusion imaging agents," said Jeff Bailey, President and CEO of Lantheus. "We are pleased to partner with JHS for the manufacture of high quality products, including NEUROLITE and DEFINITY."

Recently, Lantheus received approval from the Therapeutic Goods Administration (TGA) of Australia and the Pharmaceutical and Medical Devices Agency of Japan for JHS-manufactured NEUROLITE.

JHS also serves as an approved manufacturer of DEFINITY<sup>®</sup> Vial for (Perflutren Lipid Microsphere) Injectable Suspension for contrast-enhanced echocardiography.

# **About NEUROLITE®**

NEUROLITE® (Kit of the Preparation of Technetium Tc99m Bicisate for Injection) is a SPECT brain imaging agent for use to identify the area within the brain where blood flow has been blocked or reduced due to stroke.

#### **INDICATIONS**

NEUROLITE single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed. NEUROLITE is not indicated for assessment of functional viability of brain tissue or for distinguishing between stroke and other brain lesions.

# **CONTRAINDICATIONS**

None known.

## **Important Safety Information**

In clinical trials, NEUROLITE has been administered to 1063 subjects (255 normals, 808 patients). In the 808 patients with neurologic events, there were 11 (1.4%) deaths, none of which were clearly attributed to NEUROLITE. The following adverse effects were observed in ≤ 1% of the subjects: headache, dizziness, seizure, agitation/anxiety, malaise/somnolence, parosmia, hallucinations, rash, nausea, syncope, cardiac failure, hypertension, angina, and apnea/cyanosis.

#### **WARNINGS**

None known.

#### **PRECAUTIONS**

**General:** USE WITH CAUTION IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT. TECHNETIUM Tc99m BICISATE IS ELIMINATED PRIMARILY BY RENAL EXCRETION. WHETHER TECHNETIUM Tc99m BICISATE IS DIALYZABLE IS NOT KNOWN. DOSE ADJUSTMENTS IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT HAVE NOT BEEN STUDIED.

Patients should be encouraged to drink fluids and to void frequently during the 2-6 hours immediately after injection to minimize radiation dose to the bladder and other target organs. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

Please see full prescribing information on www.lantheus.com.

## 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 <a href="http://www.definityimaging.com">http://www.definityimaging.com</a>). Since its launch in 2001, activated DEFINITY® has been administered to more than 5.4 million patients.<sup>2</sup>

## **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<sup>®</sup> 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 <u>www.definityimaging.com</u>.

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

Lantheus Medical Imaging, Inc. is a global leader in developing, manufacturing, selling and distributing innovative diagnostic imaging agents. The Company 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 Xe 133 Gas (Xenon 133), an inhaled radiopharmaceutical imaging agent used to evaluate pulmonary function and for imaging the lungs.

Lantheus has more than 500 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.

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## References

- 1. DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2013.
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