Lantheus Receives U.S. FDA Approval of New Manufacturing Facility

February 23, 2022

On-site plant will produce DEFINITY® (Perflutren Lipid Microsphere), the leading diagnostic ultrasound enhancing agent for patients with suboptimal echocardiograms

NORTH BILLERICA, Mass., Feb. 23, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTH), an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find, Fight and Follow serious medical conditions, announced today that the U.S. Food and Drug Administration (FDA) has approved the Supplemental Drug Application (sNDA) for the Company's isolator-based drug manufacturing facility for DEFINITY ® (Perflutren Lipid Microsphere), the leading diagnostic ultrasound enhancing agent in U.S. for patients with suboptimal echocardiograms.

Lantheus constructed the specialized, in-house manufacturing facility at the Company's North Billerica, Massachusetts headquarters for purposes of producing DEFINITY and potentially other sterile vial products. Designed and constructed with industry leading partners, the 16,000 sq. ft. facility utilizes a state-of-the-art manufacturing process and has the capacity to meet the Company's current total demand for DEFINITY, while providing flexibility for potential future growth opportunities.

"Achieving approval of our on-site manufacturing facility was a Company-wide effort and represents an important step forward for Lantheus' strategy to improve the security of DEFINITY supply," said Mary Anne Heino, President and Chief Executive Officer of Lantheus. "This facility will provide the Company with supply chain redundancy and the opportunity for margin expansion as we progressively include DEFINITY inventory from this facility into our supply chain. We intend to begin shipping DEFINITY from our on-site manufacturing facility to customers immediately."

About DEFINITY®
DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension (activated) is an ultrasound enhancing 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.[2] Since its launch in 2001, more than 18 million echo studies have been performed with DEFINITY, and it is the most prescribed ultrasound enhancing agent in the U.S.[3]

DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension

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 lipid microsphere or its components.

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 accompanying full Prescribing Information, including boxed **WARNING** regarding serious cardiopulmonary reactions, on **www.definityimaging.com**.

About Lantheus Holdings, Inc.
Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB and an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find Fight and Follow® serious medical conditions. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; PYLARIFY®, a PSMA PET imaging agent for the detection of suspected recurrent or metastatic prostate cancer; PYLARIFY AI™, an artificial intelligence platform that assists in the evaluation of PSMA PET images; TechneLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine

procedures; AZEDRA® for the treatment of certain rare neuroendocrine tumors; and RELISTOR® for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc. The Company is headquartered in North Billerica, Massachusetts with offices in New Jersey, Canada and Sweden. 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, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as "current," "future," "intend," "potential," "step forward," "will" and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. 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. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) continued market expansion and penetration for DEFINITY in the face of segment competition and potential generic competition, including as a result of patent and regulatory exclusivity expirations; (ii) our ability to manufacture DEFINITY at our on-site manufacturing facility; (iii) the intellectual property protection of DEFINITY; (iv) the potential reclassification by the FDA of certain of our products and product candidates from drugs to devices with the expense, complexity and potentially more limited competitive protection such reclassification could cause; (v) the impact of the COVID-19 pandemic on our business, financial condition and prospects; and (vi) the risk and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

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

[2] Data on file, Lantheus Medical Imaging, Inc.

[3] AMR, The Echocardiography Real World Data 2020-2021, Quarterly

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