Lantheus Holdings, Inc. Announces FDA Approval of DEFINITY® Room Temperature

Nov 18, 2020

Commercially Available in Early 2021

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Nov. 18, 2020-- Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTH), the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products, today announced the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) for DEFINITY® Room Temperature (DEFINITY RT) (Perflutren Lipid Microsphere) Injectable Suspension.

"With the approval of DEFINITY RT, we expand our microbubble franchise offering to include a room temperature formulation, in addition to our market leading, refrigerated DEFINITY that our customers and patients have trusted to enhance suboptimal echocardiograms for 19 years. This approval will enable those customers who prefer a non-refrigerated product to be able to continue to benefit from our DEFINITY microbubble products," said Paul Blanchfield, Chief Commercial Officer.

Mary Anne Heino, President and Chief Executive Officer, added, "We continue to expand the offerings in our microbubble franchise. The addition of DEFINITY RT recognizes the increasing need for portability in delivery of healthcare services, as well as our commitment to partnering with innovators developing complex product formulations which include a microbubble. I am thankful to the entire Lantheus team who worked diligently to bring this new formulation to the market."

DEFINITY RT is a modified formulation of DEFINITY that allows both storage and shipment at room temperature (DEFINITY's previously approved formulation requires refrigerated storage). The activation of DEFINITY RT will be achieved using the VIALMIX® RFID device, which was approved in August 2020. This modified formulation provides clinicians an additional choice and allows for greater utility of this formulation in broader clinical settings.

The composition of matter U.S. issued patent for DEFINITY RT has an expiration date of 2035 and will be listed in the Orange Book.

About DEFINITY® and DEFINITY® RT

DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension and DEFINITY RT (Perflutren Lipid Microsphere) Injectable Suspension (activated) are ultrasound enhancing agents for use in patients with suboptimal echocardiograms (see Indications and Important Safety Information below and find full Prescribing Information at www.definityimaging.com).[1,2] DEFINITY and DEFINITY RT are engineered to produce small and consistently sized durable microbubbles to fully evaluate the left ventricle.[1,2] DEFINITY has extensive safety experience and a consistent safety profile.[3] Since its launch in 2001, more than 14 million echo studies have been performed with DEFINITY, and it is the most prescribed ultrasound enhancing agent in the U.S.[4]

DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension
DEFINITY® RT (Perflutren Lipid Microsphere) Injectable Suspension

INDICATIONS

Activated DEFINITY® and activated DEFINITY® RT (Perflutren Lipid Microsphere) Injectable Suspension are 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® and DEFINITY® RT 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® and DEFINITY® RT 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. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products. Lantheus provides a broad portfolio of products, including the echocardiography 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; 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 York, New Jersey, Puerto Rico, 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 “anticipate,” “believe,” “confident,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “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) our future operating results; (ii) the impact of the COVID-19 pandemic on our business, financial condition and prospects; (iii) the Company’s ability to successfully launch DEFINITY RT as a commercial product and the timing of the launch; (iv) the intellectual property protection of DEFINITY RT; (v) expectations for future clinical trials, the timing and potential outcomes of clinical studies and filings and other interactions with regulatory authorities; 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] DEFINITY® RT (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc.

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

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