Lantheus Holdings, Inc. Announces FDA Approval of VIALMIX® RFID Device for DEFINITY®

August 12, 2020

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Aug. 12, 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 VIALMIX®*RFID* for DEFINITY®.

VIALMIX*RFID* is a next generation activation device designed specifically for DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an intravenous ultrasound enhancing agent, and our DEFINITY modified formulation product candidate. DEFINITY is supplied as a liquid-filled glass vial and requires activation in order to create the lipid-encapsulated microbubbles. The activation rate and time are controlled by VIALMIX*RFID* through the use of radio-frequency identification technology to ensure reproducible activation of DEFINITY. The RFID tag, which is affixed to the vial label, enables the DEFINITY vial to be appropriately activated when utilized with VIALMIX*RFID* activation device.

“The approval of VIALMIX *RFID* further strengthens and extends our core microbubble franchise,” said Mary Anne Heino, President and Chief Executive Officer. “By controlling the activation rate and time, the RFID technology ensures reproducible activation of DEFINITY and reduces risks related to operator or medication errors, potentially increasing patient safety. Importantly, VIALMIX*RFID* has been designed to work with our currently approved DEFINITY vial and our DEFINITY modified formulation product candidate. I am grateful to the entire Lantheus team that worked tirelessly to bring this next generation activation device to the market.”

A U.S. issued patent on the use of the new VIALMIX*RFID* with an expiration date of 2037 has been listed in the Orange Book, and additional patent applications have been submitted in major markets throughout the world.

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 13 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.

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. 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) regulatory risks related to our DEFINITY® modified formulation candidate; (iv) risks that the anticipated benefits of the acquisition of Progenics Pharmaceuticals, Inc. or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (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., 2017.

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

[3]

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Source: Lantheus Holdings, Inc.