Lantheus Announces the FDA Approval of DEFINITY® (Perflutren Lipid Microsphere) for Pediatric Patients

March 4, 2024 at 8:30 AM EST

DEFINITY is the #1 utilized ultrasound enhancing agent in the U.S. for patients with suboptimal echocardiograms

BEDFORD, Mass., March 04, 2024 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow® disease to deliver better patient outcomes, today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) for DEFINITY® (Perflutren Lipid Microsphere) as an ultrasound enhancing agent for use in pediatric patients with suboptimal echocardiograms. This approval represents a significant step forward in pediatric medicine, providing healthcare professionals with a valuable tool to opacify the left ventricular chamber and better identify the left ventricular endocardial border. Currently, DEFINITY is the most utilized, extensively studied, and a trusted diagnostic ultrasound enhancing agent in the U.S.[1-3]

“The expanded indication for DEFINITY is a testament to the rigorous research and development efforts undertaken by Lantheus to address unmet medical needs of pediatric patients,” said Jean-Claude Provost, MD, Chief Medical Officer. “We are proud that this approval will extend the benefits of DEFINITY to healthcare professionals who work with these young individuals.”

Clinical studies have substantiated the efficacy and safety of DEFINITY in pediatric patients.

"While DEFINITY has long demonstrated its effectiveness in providing better outcomes in adults over the past two decades, this new FDA decision offers a critical diagnostic tool for pediatric heart patients and their families,” said Kassa Darge, MD, PhD, Radiologist-in-Chief and Chair of the Department of Radiology at Children’s Hospital of Philadelphia. “This approval will offer a valuable alternative to pediatric cardiologists trying to do imaging work up in challenging pediatric cardiac cases.”

The FDA decision was based on usage data from three pediatric clinical trials conducted with DEFINITY: the Golding study, which evaluated 40 patients, ranging from 1 month to 17 years of age, with significant cardiovascular disorders, including heart transplant, Kawasaki disease or congenital cardiovascular anomaly; the Fine study, which evaluated 36 patients, ranging from 10 to 21 years of age, who had previously undergone a heart transplant; and the Kutty study, a retrospective medical record review of 113 pediatric patients, ranging from 5 to 21 years, who had a diagnosis of known congenital or acquired heart disease or suspected cardiac disease. These studies evaluated the use of DEFINITY in a total of 189 patients (107 (56.5%) were male and 82 (43.5%) were female).[4-6]

The Golding study, together with supportive data from the Fine and Kutty studies, demonstrate that left ventricular opacification with DEFINITY (cumulative doses ranging from 6 µL/kg to 20 µL/kg) is successful in pediatric patients and that ultrasound contrast provides important information to guide management in such patients. In the Golding study, both the ability to detect wall motion abnormalities and the ability to perform ejection fraction determinations were improved in the majority (70% and 80%, respectively) of subjects. The Kutty and Fine studies each reported successful left ventricular opacification in all participants. In the Kutty study, wall motion and/or myocardial perfusion wall motion abnormalities were identified in 13 (11.5%) of the patients (all identified during stress testing), and the number of left ventricular segments visualized improved from 13 ± 1 per patient without contrast to 16 ± 1 segments per patient with contrast across all patients. The Fine study identified regional wall motion abnormalities detected in three patients (8.3%, n=36), and demonstrated successful myocardial perfusion imaging in 32 patients (88.9%), with imaging in some patients complicated by movement and/or insufficient heart rate factors.[4-6]

All reported adverse events across all trials were mild, brief and reversible without intervention. Specifically, the Golding study reported no AEs among study participants; the Fine study reported that 33% of patients experienced mild AEs (palpitations, headache, nausea and shortness of breath) attributed to stress test procedures and not as a result of DEFINITY administration; and the Kutty study reported 11% of patients experienced AEs with no differences between DEFINITY and those patients who did not receive DEFINITY in frequencies of adverse events (chest/back/neck pain, headache, fatigue, dizziness, shortness of breath).[4-6]

About DEFINITY®

DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension is an ultrasound enhancing agent approved for use in patients with suboptimal echocardiograms (see Indications and Important Safety Information below and find full Prescribing Information at www.definityimaging.com).[6] DEFINITY is the most utilized, extensively studied and a trusted ultrasound enhancing agent with more than 20 years in the market.[1-3]

DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension

INDICATIONS

DEFINITY® is indicated, after activation, for use in adult and pediatric patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

CONTRAINDICATIONS

DEFINITY® is contraindicated in patients with known or suspected hypersensitivity to perflutren lipid microsphere or its components, such as polyethylene glycol (PEG) *[see Warnings and Precautions (5.2) and Description (11)]*.

IMPORTANT SAFETY INFORMATION

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. 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 [*see Warnings and Precautions (5.1)*].**

In post-marketing use, rare but serious cardiopulmonary or hypersensitivity reactions have been reported during or shortly following perflutren and PEG-containing microsphere administration [*see Adverse Reactions (6)*]. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions and/or with pre-existing PEG hypersensitivity [*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 conditions.

Patients with sickle cell disease may be at higher risk of painful crisis and DEFINITY® should be administered with caution.

Healthcare providers and pediatric specialists are encouraged to review the updated prescribing information for DEFINITY, when available, to incorporate the expanded indication into their clinical practice.

Please see accompanying full Prescribing Information for DEFINITY®, including boxed **WARNING** regarding serious cardiopulmonary reactions, on www.definityimaging.com.

About Lantheus
Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. 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 "aim," "will" and other similar terms. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus 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 Lantheus' actual results to materially differ from those described in the forward-looking statements are discussed in Lantheus' filings with the Securities and Exchange Commission (including those described in the Risk Factors section in Lantheus' Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q).

[1]Data on file, Lantheus.
[2]Embase and Medline Search, May 2018; Data on file, Lantheus.
[3]©2021 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.
[4]Fine, N. M., et. al (2021). Myocardial Contrast Echocardiography for Cardiac Allograft Vasculopathy: Feasibility of Real-Time Myocardial Contrast Echocardiography to Detect Cardiac Allograft Vasculopathy in Pediatric Heart Transplant Recipients. Journal of the American Society of Echocardiography.
[5]Kutty, S., et al (2016). Safety and Efficacy of Cardiac Ultrasound Contrast in Children and Adolescents for Resting and Stress Echocardiography. Journal of the American Society of Echocardiography.
[6] DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc.

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