GE Healthcare and Lantheus Announce Start of a Phase 3 Clinical Trial of Flurpiridaz, an Investigational Agent Being Evaluated for the Detection of Coronary Artery Disease

July 31, 2018

BOSTON & NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jul. 31, 2018-- GE Healthcare and Lantheus Holdings, Inc. (NASDAQ: LNTH), parent company of Lantheus Medical Imaging, Inc. (collectively “Lantheus”), have started a second Phase 3 clinical trial of Flurpiridaz ^{18}F (called the AURORA study), an investigational agent being evaluated for the detection of coronary artery disease (CAD), the most common form of heart disease.[1] CAD affects an estimated 15.5 million Americans 20 years of age or older[2] and is the leading cause of death in the United States[1] and in Europe, where CAD is responsible for 19% of all deaths among men and 20% of deaths among women each year. [3]

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180731005219/en/

The AURORA study is an international, multicenter study to evaluate diagnostic efficacy of Flurpiridaz ^{18}F Injection positron-emission tomography (PET) myocardial perfusion imaging (MPI) in the detection of CAD. In this prospective, open-label, study, patients with suspected CAD, for whom an intracoronary angiography (ICA) has been indicated, will undergo a single-photon emission computed tomography (SPECT) MPI and Flurpiridaz ^{18}F Injection PET MPI prior to the performance of coronary angiography. The primary endpoint is the diagnostic efficacy (sensitivity and specificity) of Flurpiridaz ^{18}F Injection PET MPI for the detection of significant CAD. The first patient was enrolled in the study in June 2018. A total of 650 patients will be enrolled, with the last patient follow-up projected to occur in August 2020.

Kevin O’Neill, General Manager of Core Imaging for GE Healthcare, said, “We are thrilled to see this critical stage of the study move forward. We are committed to the development of a potential new diagnostic option for clinicians and their CAD patients in the future.”

Mary Anne Heino, President and CEO of Lantheus, commented, “The second Phase 3 study of Flurpiridaz ^{18}F represents a significant milestone in the development of this promising investigational agent. Importantly, it illustrates our strong collaboration with GE Healthcare, and we look forward to the continued progress of the clinical program.”

For more information abouttheAURORA study, please visit https://clinicaltrials.gov/ct2/show/NCT03354273.

Forward-Looking Statements
This document contains "forward-looking statements" - that is, statements related to future, not past, events. In this context, forward-looking statements often address our expected future business and financial performance and financial condition, and often contain words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "see," "will," "would," “estimate,” “forecast,” "target," “preliminary,” or “range.” Forward-looking statements are based on current plans, estimates, and expectations that are subject to risks, uncertainties, and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. The inclusion of such statements should not be regarded as a representation that such plans, estimates or expectations will be achieved. Important factors that could cause actual results to differ materially from such plans, estimates, or expectations include, among others: events could cause the AURORA study to be stopped; the AURORA study could fail to meet its primary endpoint; regulatory agencies may reject the study data or fail to approve our new drug application; our collaboration with Lantheus could encounter issues that lead to delays or additional problems completing the development plan; changes in general economic and/or industry-specific conditions; actions by third parties, including government agencies could delay or stop development; and other risk factors as detailed from time to time in GE’s respective reports filed with the U.S. Securities and Exchange Commission (SEC), including GE’s annual reports on Form 10-K, periodic quarterly reports on Form 10-Q, periodic current reports on Form 8-K, and other documents filed with the SEC. The foregoing list of important factors is not exclusive. Any forward-looking statements apply only as of the date of this communication. GE undertakes no obligation to update any forward-looking statements, whether as a result of new information or development, future events, or otherwise, except as required by law. Readers are cautioned not to place undue reliance on any of these forward-looking statements.

About Flurpiridaz
In 2017, GE Healthcare and Lantheus Holdings, Inc, parent company of Lantheus Medical Imaging, Inc, announced the signing of a definitive license agreement for the continued Phase 3 development and worldwide commercialization of Flurpiridaz^{18}F. Under this agreement, GE Healthcare will lead and fund the development of Flurpiridaz ^{18}F, including the second Phase 3 clinical study. GE Healthcare will also have exclusive worldwide rights for the commercialization of Flurpiridaz^{18}F. Lantheus will collaborate in both the development and commercialization process through a joint steering committee. Lantheus also maintains the option to co-promote the agent in the United States.

About GE Healthcare:
GE Healthcare is the $19 billion healthcare business of GE (NYSE: GE). As a leading provider of medical imaging, monitoring, biomanufacturing, and cell and gene therapy technologies, GE Healthcare enables precision health in diagnostics, therapeutics, and monitoring through intelligent devices, data analytics, applications, and services. With over 100 years of experience in the healthcare industry and more than 50,000 employees globally, the company helps improve outcomes more efficiently for patients, healthcare providers, researchers, and life sciences companies around the world. Follow us on *Facebook*, *LinkedIn*, *Twitter*, *and* *The Pulse* for latest news, or visit our website, www.gehealthcare.com, for more information.

About Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.
Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. Lantheus 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 (Xenon Xe 133 Gas), an inhaled radiopharmaceutical imaging agent used to evaluate pulmonary function and for imaging the lungs. Lantheus is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

References:

1. National Heart, Lung, and Blood Institute website. Coronary heart disease (also known as coronary artery disease). http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_WhoIsAtRisk.html. Accessed July 25, 2018.
2. Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics–2016 update: a report from the American Heart Association. *Circulation*. 2016;133:e38-e360.
3. European Heart Network. European Cardiovascular Disease Statistics, 2017edition**.** http://www.ehnheart.org/images/CVD-statistics-report-August-2017.pdf. Accessed July 25, 2018.

View source version on businesswire.com: https://www.businesswire.com/news/home/20180731005219/en/

Source: Lantheus Holdings, Inc.

GE Healthcare
Claudia Scarpelli, +49 173 5811032
claudia.scarpelli@ge.com
or
Lantheus
Meara Murphy, + 1 978-671-8508
meara.murphy@lantheus.com