



GE Healthcare and Lantheus Phase III Clinical Trial Finds [18F]flurpiridaz PET Radiotracer Could Improve Detection of Coronary Artery Disease

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- Phase III clinical trial of [18F]flurpiridaz PET diagnostic radiopharmaceutical meets co-primary endpoints for detecting Coronary Artery Disease (CAD)
- Trial also met its first key secondary endpoint, demonstrating higher diagnostic efficacy for [18F]flurpiridaz PET compared to SPECT Myocardial Perfusion Imaging (MPI)
- With a half-life roughly 12 times longer than currently approved cardiac PET radiotracers, if approved, [18F]flurpiridaz has the potential to expand patient access to PET MPI
- This radiotracer is part of GE Healthcare's pipeline of Molecular Imaging diagnostics aiming to increase diagnostic accuracy and improve patient outcomes across key care areas

CHALFONT ST GILES, United Kingdom and NORTH BILLERICA, Mass., Sept. 13, 2022 (GLOBE NEWSWIRE) -- GE Healthcare and Lantheus Holdings Inc (NASDAQ: LNTH) have announced that the recent Phase III clinical trial of their investigational radiotracer, [18F]flurpiridaz, has met its co-primary endpoints of exceeding a 60 percent threshold for both sensitivity and specificity for detecting Coronary Artery Disease (CAD). The findings, shared at the American Society of Nuclear Cardiology (ASNC) Congress, in Florida, U.S., also demonstrate [18F]flurpiridaz Positron Emission Tomography (PET) has higher diagnostic efficacy and image quality in patients with suspected CAD, compared with Single Photon Emission Computed Tomography (SPECT) Myocardial Perfusion Imaging (MPI), the predominant procedure used in nuclear cardiology today. SPECT MPI represents approximately 6 million procedures per year in the U.S.ⁱ

The Phase III Open-Label Study, which involved over 600 patients across sites in the U.S., Europe and Canada assessed the diagnostic efficacy of [18F]flurpiridaz in detecting CAD, the most common form of heart diseaseⁱⁱ and the leading cause of death globallyⁱⁱⁱ, with invasive coronary angiography as a standard of truth. More than 120 million people are affected by CAD globally each year^{iv} and in the U.S. alone, approximately 20 million adults have CAD, with nearly 383,000 deaths recorded in 2020^v.

If approved, this investigational agent would offer the advantages of ¹⁸F, with broad available distribution and a half-life of almost two hours, removing the need for it to be manufactured in the immediate vicinity of the imaging department. This longer half-life could also make Flurpiridaz (¹⁸F) Injection suitable for exercise stress testing, which is not feasible with existing cardiac PET radiotracers.

Dr. Tim Bateman, MD, FACC, co-director of the Cardiovascular Radiologic Imaging Program at Saint Luke's Hospital, Missouri, US, shared: "These results are truly promising for the nuclear cardiology community and CAD patients. From ASNC's inception, its leaders have laid out the specifications for an ideal myocardial perfusion tracer. In my view [18F]flurpiridaz could meet this goal, expanding how PET MPI can be used to image CAD patients moving forward."

Dr. Francois Tranquart, MD, PhD, Global Head of Clinical Development for GE Healthcare Pharmaceutical Diagnostics, Research and Development, said: "The positive Phase III trial results are a key step towards future approval of Flurpiridaz (¹⁸F) Injection as a potential new cardiac PET agent which could improve the detection of coronary artery disease. This is another example of GE Healthcare investing in our portfolio of Molecular Imaging products to help improve diagnostic accuracy and patient outcomes."

GE Healthcare has led the funding and development of [18F]flurpiridaz, and, if the imaging agent is approved, will have global commercialization rights. Lantheus has collaborated on the development and will also collaborate on potential commercialization through a joint steering committee. Lantheus is entitled to royalties based on commercial sales.

GE Healthcare's Pharmaceutical Diagnostics unit is a global leader in imaging agents used to support around 100 million procedures per year globally, equivalent to three patients every second. Its Molecular Imaging portfolio combines an innovative pipeline with established proprietary products across cardiology, neurology and oncology.

About GE Healthcare:

GE Healthcare is the \$17.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through

intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 48,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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About Lantheus

With more than 60 years of experience in delivering life-changing science, Lantheus is committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. Lantheus is headquartered in Massachusetts and has offices in New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

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ⁱ Data on File: AMR Market Guide 2021.

ⁱⁱ [WHO Factsheet 2020. Cardiovascular diseases \(CVDs\)](#). 11 June 2021.

ⁱⁱⁱ [Global Epidemiology of Ischemic Heart Disease: Results from the Global Burden of Disease Study](#). July 23 2020.

^{iv} [Global Epidemiology of Ischemic Heart Disease: Results from the Global Burden of Disease Study](#). July 23 2020.

^v [Centers for Disease Control and Prevention. Heart Disease Facts](#). Accessed July 15 2022.



Source: Lantheus Holdings, Inc.

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