Current Agreements

Dealdoc

Development and marketing agreement for flurpiridaz F 18

Lantheus Medical Imaging
GE Healthcare

Feb 22 2017

Development and marketing agreement for flurpiridaz F 18

Companies:	Lantheus Medical Imaging GE Healthcare
Announcement date:	Feb 22 2017
Deal value, US$m:	65 : sum of upfront and milestone payments

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Details

Announcement date:	Feb 22 2017
Industry sectors:	Biotech Diagnostic Medical device Research tools Services
Compound name:	flurpiridaz F 18
Asset type:	Compound
Therapy areas:	Cardiovascular » Coronary artery disease Diagnostics » Imaging
Technology types:	Diagnostics » Imaging » Molecular and nuclear » PET (Positron Emission Tomography)
Deal components:	Development Marketing Option
Stages of development:	Phase III Regulatory
Geographic focus:	Worldwide

Financials

Deal value, US$m:	65 : sum of upfront and milestone payments
Upfront, US$m:	5 : upfront cash payment
Milestones, US$m:	60 : regulatory and sales milestones payments
Royalty rates, %:	15 : tiered double-digit royalties on U.S. sales 5 : mid-single-digit royalties on sales outside of the U.S
Semi-quant royalties:	Mid single digit Double digit

Termsheet

Parties Involved

- **GE Healthcare**
- **Lantheus (via subsidiary Lantheus Medical Imaging, Inc.)**

Collaboration Scope

The agreement between GE Healthcare and Lantheus covers the **continued Phase III development and global commercialization** of **[18F]flurpiridaz**, a novel PET myocardial perfusion imaging (MPI) agent designed to improve the diagnosis of **coronary artery disease (CAD)**. GE Healthcare is leading the funding and development, while both parties collaborate via a **joint steering committee** on development and commercialization efforts.

Rights & Responsibilities

GE Healthcare:

Funds the **second Phase III clinical study**.

- Responsible for obtaining **worldwide regulatory approvals**.
- Holds **global commercialization rights**, if the agent is approved.
- Leads development in the **U.S., Japan, Europe, and Canada**.

Lantheus:

Collaborates on development and commercialization through the **joint steering committee**.

- Retains the **option to co-promote in the U.S.**.
- Entitled to **royalties on sales**, if approved.
- **Shared Governance**: Development and commercialization plans are overseen by a joint steering committee.

Financial Terms

- **Upfront Payment**: **USD 5 million** to Lantheus.
- **Milestone Payments**: Up to **USD 60 million** in development, regulatory, and sales-based milestones.

Royalties:

Tiered double-digit royalties on **U.S. sales**.

- **Mid-single-digit royalties** on **sales outside the U.S.**.
- **Co-promotion Option**: Lantheus retains the right to **co-promote in the U.S.**.

Regulatory Approval

- The **Phase III trial**, completed and presented in September 2022, **met its co-primary endpoints** for sensitivity and specificity in detecting CAD and **demonstrated superior diagnostic efficacy** compared to SPECT MPI.
- The trial also met the **first key secondary endpoint**, highlighting the radiotracer's higher image quality and diagnostic accuracy.
- Regulatory approval is pending but expected, contingent on these positive results.

Overall Summary

GE Healthcare and Lantheus formed a global collaboration for the late-stage development and commercialization of **[18F]flurpiridaz**, a next-generation PET imaging agent for CAD. **GE Healthcare** leads development and funding, with **Lantheus** participating through governance, optional co-promotion, and royalty entitlement. Clinical results from 2022 indicate strong potential for the agent to improve CAD diagnosis, with a **longer half-life** enabling **broader patient access** and **stress-testing compatibility**. The agreement positions both parties to benefit from the product's commercial success, subject to regulatory approval.

Press Release

September 2022

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

Sept. 13, 2022 12:05 UTC

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, England & NORTH BILLERICA, Mass.--(BUSINESS WIRE)-- 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.Si.

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 yeariv and in the U.S. alone, approximately 20 million adults have CAD, with nearly 383,000 deaths recorded in 2020v.

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.

Follow us on Facebook, LinkedIn, Twitter, and Insights for the latest news, or visit our website www.gehealthcare.com for more information.

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.

February 2017

NORTH BILLERICA, Mass. & CHALFONT ST GILES, United Kingdom--(BUSINESS WIRE)--Lantheus Medical Imaging, Inc. (“LMI”), a subsidiary of Lantheus Holdings, Inc. (“Lantheus”) (NASDAQ: LNTH), and GE Healthcare (NYSE:GE), today announced the signing of a term sheet relating to the continued Phase III development and worldwide commercialization of flurpiridaz F 18, an investigational positron emission tomography (PET) myocardial perfusion imaging (MPI) agent that may improve the diagnosis of coronary artery disease (CAD).

“Pursuing this agreement with LMI will further strengthen our nuclear medicine portfolio and demonstrates our commitment to cardiovascular PET imaging. It is a key focus of our strategy to increase the number of tools at the disposal of clinicians around the world diagnosing and treating patients with cardiovascular disease.”

Under the proposed transaction, GE Healthcare would fund the second Phase III flurpiridaz F 18 clinical study, worldwide regulatory approvals and its worldwide launch and commercialization, with LMI collaborating in both development and commercialization through a joint steering committee. LMI would also maintain the option to co-promote the agent in the U.S. GE Healthcare’s development plan would focus on obtaining regulatory approval in the U.S., Japan, Europe and Canada.

Mary Anne Heino, President and CEO of Lantheus commented, “We are excited about the prospect of GE Healthcare being our global partner to complete the development of flurpiridaz F 18 and bring this next generation agent to market, as they touch every level of the PET diagnostic delivery continuum and share our commitment to serving the nuclear medicine community. The collaboration would enable us to participate in the long-term economic success of flurpiridaz F 18. LMI will also continue to advance our other pipeline assets and pursue additional near-term business development opportunities to drive growth.”

Emmanuel Ligner, General Manager, Core Imaging, GE Healthcare, said: “Pursuing this agreement with LMI will further strengthen our nuclear medicine portfolio and demonstrates our commitment to cardiovascular PET imaging. It is a key focus of our strategy to increase the number of tools at the disposal of clinicians around the world diagnosing and treating patients with cardiovascular disease.”

Under the proposed transaction, LMI would receive a USD 5 million upfront cash payment and, if successful, up to USD 60 million in regulatory and sales milestones payments, plus tiered double-digit royalties on U.S. sales and mid-single-digit royalties on sales outside of the U.S. LMI also would receive an option to co-promote in the U.S. Subject to satisfactory due diligence and necessary approvals, the parties anticipate entering into a definitive agreement for the proposed transaction in the second quarter of 2017. However, there is no assurance that the parties will enter into a definitive agreement on these terms or at all.

About Flurpiridaz F 18 and Coronary Artery Disease Flurpiridaz F 18, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1)1, was designed to be a novel PET imaging agent that may better evaluate patients with known or suspected CAD, which is the most common form of heart disease2, affecting an estimated 15.5 million Americans 20 years of age or older3. CAD is the leading cause of death in the United States for both men and women2. Each year more than 400,000 Americans die from CAD2. In the first phase 3 study, flurpiridaz F 18 demonstrated improved CAD detection and reduced radiation exposure over standard single photon emission computed tomography (SPECT). In subgroup analyses, the risk-benefit profile of flurpiridaz F 18 PET imaging appeared to be favorable in women, obese patients and patients with multi-vessel disease. It is important to note that, with a 110 minute half-life, flurpiridaz F 18 can be used in conjunction with treadmill exercise, which is not feasible with other currently available PET tracers for MPI.

About PET and MPI PET imaging or a PET scan is a type of nuclear medicine imaging procedure4 that provides information about the function and metabolism of the body’s organs, unlike computed tomography (CT) or magnetic resonance imaging (MRI), which primarily show anatomy and structure5. MPI is a non-invasive test that utilizes a small amount of radioactive material (radiopharmaceutical) injected into the body to depict the distribution of blood flow to the heart. MPI is used to identify areas of reduced blood flow to the heart muscle. The test is typically conducted under both rest and stress conditions, after which physicians examine and compare the two scans and predict whether the patient has significant coronary artery disease6. Although SPECT is most commonly used for MPI7, PET imaging has gained considerable support and use in the field of cardiovascular imaging, as it offers many advantages to SPECT, including higher spatial and contrast resolution, resulting in higher image quality and improved diagnostic accuracy, accurate attenuation correction and risk stratification8.

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. LMI provides

a broad portfolio of products, which are primarily used for the diagnosis of cardiovascular diseases. LMI's 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. LMI is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

About GE Healthcare GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges. From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients. For more information about GE Healthcare, visit www.gehealthcare.com.

Filing Data

Not available.

Contract

Not available.