Lantheus Medical Imaging and FUJIFILM RI Pharma Renew Long-Term License and Distribution Agreement for Cardiolite and Neurolite in Japan

The Associated Press

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jan 3, 2013--Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced that it has entered into a new agreement with FUJIFILM RI Pharma Co., Ltd. (FRI) to license and distribute Cardiolite ® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) and Neurolite ® (Kit for the Preparation of Technetium Tc99m Bicisate for Injection) in Japan. Under the terms of the 10-year agreement effective January 1, 2013, which immediately follows an earlier 10-year agreement with FRI, Lantheus will continue to supply FRI with Cardiolite ® and Neurolite ® in finished form as well as provide the raw materials to manufacture and sell the products in unit dose form. Cardiolite ® and Neurolite ® are technetium-based radiopharmaceutical imaging agents used in single-photon emission computed tomography (SPECT).

“We are pleased to continue our long-term collaborative relationship with FRI, which we’ve successfully developed over the past ten years,” said Don Kiepert, President and Chief Executive Officer, Lantheus Medical Imaging. “Japan represents one of the largest markets for imaging agents worldwide. As such, we share a joint commitment with FRI to provide proven, reliable medical imaging technologies to healthcare providers and patients. This commitment includes ensuring continued access to Cardiolite ® and Neurolite ® for SPECT imaging.” “Lantheus is the ideal partner for FRI in the Japanese diagnostic imaging market as we have a shared view of the clinical value and benefits of radiopharmaceuticals in the diagnosis of disease,” said Yoshiro Kumano, President and Chief Executive Officer, FRI. “Our customers are our top priority, and we will continue to meet their needs by offering Cardiolite ® and Neurolite ® for use in cardiovascular and brain imaging, respectively.” About Cardiolite ® Cardiolite ® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) has played a vital role in the diagnosis and management of patients with known or suspected coronary artery disease for almost two decades.

Indications and Usage: Myocardial Imaging: Cardiolite ® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. Cardiolite ® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g. exercise or pharmacologic stress in accordance with the pharmacologic stress agent’s labeling).

Contraindications: None known.

Important Safety Information: Cardiolite ® has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during Cardiolite ® imaging. The most frequently reported adverse events include headache, chest pain/angina, ST segment changes on ECG, nausea, and abnormal taste and smell. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Section 5.2). Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction and cerebrovascular events.

Warnings and Precautions: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Caution should be exercised and emergency equipment should be available when administering Cardiolite ®. Before administering Cardiolite ® patients should be asked about the possibility of allergic reactions to either Cardiolite ® or MIRALUMA ®. MIRALUMA ® is an identical compound used in breast imaging. The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

For full prescribing information, please visit www.cardiolite.com. Cardiolite ® is a registered trademark of Lantheus Medical Imaging, Inc.

About Neurolite ® Neurolite ® (Kit for the Preparation of Technetium Tc99m Bicisate for Injection) is a SPECT brain imaging agent for localization of stroke in patients in whom stroke has already been diagnosed.

Indications: Neurolite ® single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed. Neurolite ® is not indicated for assessment of functional viability of brain tissue or for distinguishing between stroke and other brain lesions.

Contraindications: None known.

Important Safety Information: In clinical trials, Neurolite ® has been administered to 1063 subjects (255 normals, 808 patients). In the 808 patients with neurologic events, there were 11 (1.4%) deaths, none of which were clearly attributed to Neurolite ®. The following adverse effects were observed in ≤ 1% of the subjects: headache, dizziness, seizure, agitation/anxiety, malaise/somnolence, parosmia, hallucinations, rash, nausea, syncope, cardiac failure, hypertension, angina, and apnea/cyanosis.

Warnings: None known.

Precautions: General: Use with caution in patients with renal or hepatic impairment. Technetium Tc99m Bicisate is eliminated primarily by renal excretion. Whether Technetium Tc99m Bicisate is dialyzable is not known. Dose adjustments in patients with renal or hepatic impairment have not been studied.

Patients should be encouraged to drink fluids and to void frequently during the 2-6 hours immediately after injection to minimize radiation dose to the bladder and other target organs. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

For full prescribing information, please visit www.lantheus.com. Neurolite ® is a registered trademark of Lantheus Medical Imaging, Inc.

About Lantheus Medical Imaging, Inc. Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The Company’s proven success in the field of diagnostic imaging provides a strong platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. Lantheus imaging products include the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an ultrasound contrast agent for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border, ABLAVAR ® (gadofosveset trisodium), a first-in-class magnetic resonance agent indicated for the evaluation of aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease, TechneLite ® (Technetium Tc99m Generator), Cardiolite ® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride Tl 201 Injection). Lantheus has approximately 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. 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. Such forward-looking statements are subject to risks and uncertainties that may be described from time to time in our filings with the Securities and Exchange Commission. 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.

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