Lantheus Medical Imaging, Inc. Presents Phase 1 Data Highlighting Safety, Dosimetry and Tolerability of Novel PET Heart Failure Imaging Agent at SNM Annual Meeting

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N. BILLERICA, Mass. (June 8, 2010) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced Phase 1 data for its novel heart failure Positron Emission Tomography (PET) imaging agent, LMI 1195, which is in development for the evaluation of patients at risk of heart failure or sudden cardiac death. The preliminary data showed that LMI 1195 can render high-quality, well-defined images of the cardiac autonomic nervous system, which helps regulate the electrical activity of the heart and its ability to contract[1]. In addition to the high and uniform myocardial uptake, the radiotracer cleared quickly from the blood and had a favorable safety and dosimetry profile.

The Phase 1 data were featured in two separate poster presentations at the SNM 57th Annual Meeting in Salt Lake City. Data examining the myocardial uptake of LMI 1195 were presented by Yi-Hwa Liu, Ph.D., Associate Professor of Medicine (Cardiology), Yale School of Medicine on Monday, June 7 (poster #798819), and radiation dosimetry data are being presented by Joel Lazewatsky, Ph.D., Principal Research Scientist, Lantheus Medical Imaging, Inc., today, Tuesday, June 8 (poster #797609).

“There has been limited understanding to date of the functioning of the heart’s autonomic nervous system through imaging,” said L. Veronica Lee, M.D., Medical Director at Lantheus Medical Imaging. “The data from this Phase 1 study of LMI 1195 demonstrating safety and tolerability in healthy subjects are encouraging, as we prepare to initiate Phase 2 clinical trials later this year. Although preliminary, these data suggest that PET imaging with LMI 1195 has the potential to provide physicians with a clear view of the autonomic nervous system of the heart, which would be helpful for the identification and evaluation of heart failure patients. They also suggest that physicians may be able to view specific regions of the heart, which could potentially facilitate diagnosis and evaluation of heart failure.”

The Phase 1 study was an open-label, non-randomized, single-dose study designed to estimate the radiation dosimetry of LMI 1195 in healthy subjects undergoing a PET scan, to evaluate the safety and tolerability of the tracer, and to assess PET imaging parameters and image quality. Twelve healthy subjects received a single intravenous (IV) bolus injection of 150-250 megabecquerel (MBq) of LMI 1195. Dynamic PET images were obtained of the heart for 10 minutes, followed by sequential whole body images for approximately five hours. Blood samples were obtained and heart rate, electrocardiogram and blood pressure were monitored prior to and during imaging. Residence times were determined from multi-exponential regression of regions of interest (ROI) data normalized by injected dose. Radiation dose estimates were calculated using Organ Level INternal Dose Assessment EXponential Modeling (OLINDA/EXM). Myocardial (M), lung, liver (LI), and blood pool standardized uptake values were determined at different time intervals.

The data demonstrated that LMI 1195 yields a radiation dose comparable to that of other commonly-used PET radiopharmaceuticals, and that good image quality is possible at the given dose. There were no adverse events associated with LMI 1195 in this study. The four highest-dose organs and their respective mean dose estimates were urinary bladder wall, 3.5-hour void (0.10 ± 0.020 mSv/MBq), kidneys (0.083 ± 0.014 mSv/MBq), thyroid (0.066 ± 0.011 mSv/MBq) and small intestine (0.046 ± 0.008 mSv/MBq). Mean effective dose was 0.026 ± 0.0012 mSv/MBq. Approximately 1.6 percent of the injected dose (ID) was seen in the myocardium initially, remaining above 1.5 percent of ID (decay-corrected) through four hours after injection. M/LI ratio was initially approximately equal increasing to more than two at four hours. Blood radioactivity cleared quickly and lung activity was low throughout the study.

The findings were augmented by preliminary results observed in six healthy subjects at a single clinical trial site that showed that LMI 1195 cleared quickly from the blood and demonstrated a favorable biodistribution for early cardiac imaging. Regional and global myocardial activity peaked within the first 10 minutes and reached a plateau at approximately 60 minutes post injection. Attenuation corrected images were reoriented into standard cardiac specific axes, and the maximal regional myocardial uptake was quantified on a sector-by-sector basis. The heart images were divided into three short axis slices and four radial sectors, and mean regional uptake for each sector was calculated. Activity was expressed as Bq/ml. There was no significant variation (p=0.69, ANalysis Of Variance (ANOVA)) in regional myocardial uptake at this time around the circumference of the heart. There was also no significant (p=0.08, ANOVA) base-to-apex gradient in myocardial uptake.

“We believe that PET imaging with LMI 1195 has the potential to change how heart failure patients are evaluated,” added Dana

Washburn, M.D., Vice President, Clinical Development and Medical Affairs, Lantheus Medical Imaging, Inc. "Lantheus is committed to advancing our PET imaging pipeline because of the power of PET technology to further improve cardiac imaging."

About LMI1195 and Heart Failure

LMI 1195 is a novel F-18 tracer designed to use positron emission tomography to improve imaging of cardiac neuronal function. LMI 1195 has completed Phase 1 clinical trials. In preclinical studies, LMI 1195 showed promise as a heart failure imaging agent with high cardiac sympathetic nervous system uptake.

About Heart Failure

Heart failure is a serious medical condition, in which the heart muscle progressively loses its ability to pump blood, that affects more than five million people in the United States and results in about 1.1 million hospitalizations and 300,000 deaths each year[2,3]. Patients with heart failure are six to nine times more likely than the general population[4] to suffer sudden cardiac death as a result of abnormal cardiac neuronal function resulting in a fatal arrhythmia. According to the American Heart Association, the total cost of heart failure is estimated to be $37.2 billion in 2009, putting significant health and financial burdens on patients, their families and society as a whole. Currently, diagnosing heart failure is based on presenting symptoms, patient self-reports, physical exams, tests and a patient's medical history, none of which focus on actual cardiac neuronal function.

About Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for more than 50 years, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The company's proven success in discovering, developing and marketing innovative medical imaging agents 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, 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 more than 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. For more information, visit www.lantheus.com.

1. American Heart Association. Autonomic Nervous System. http://www.americanheart.org/presenter.jhtml?identifier=4463. Accessed on May 27, 2010.
2. National Heart Lung and Blood Institute. What is Heart Failure? http://www.nhlbi.nih.gov/health/dci/Diseases/Hf/HF_WhatIs.html. Accessed on May 27, 2010.
3. American Heart Association. News Release: Updated Heart Failure Guidelines Focus on Key Research Findings, Clinical Advances. http://www.newsroom.heart.org/index.php?s=43&item=699. Accessed on May 27, 2010.
4. American Heart Association. Heart Disease and Stroke Statistics, 2009 Update. http://www.americanheart.org/downloadable/heart/1240250946756LS-1982%20Heart%20and%20Stroke%20Update.042009.pdf. Accessed on May 27, 2010