

Lantheus Medical Imaging, Inc. Presents Preliminary Phase 2 Data With Flurpiridaz F 18 (BMS747158), a Novel PET Cardiac Imaging Agent, at the American College Of Cardiology 59th Annual Scientific Session

March 16, 2010 4:03 PM ET

-- Single-Center Data Suggest Significantly Improved Diagnostic Accuracy and Specificity With New PET Agent Versus SPECT --

N. BILLERICA, Mass. (March 16, 2010) – [Lantheus Medical Imaging, Inc.](#), a worldwide leader in diagnostic imaging, today announced preliminary data on flurpiridaz F 18 (formerly known as BMS747158), its novel compound in development as a Positron Emission Tomography (PET) myocardial perfusion imaging (MPI) agent. The study of nine patients compared rest-stress flurpiridaz F 18 PET MPI, with rest-stress technetium-99m (Tc-99m) labeled single photon emission computed tomography (SPECT) for the detection and evaluation of coronary artery disease (CAD). Preliminary results from the single-center study suggest that compared to SPECT MPI, flurpiridaz F 18 PET MPI has a higher diagnostic specificity for detecting right coronary artery disease and a higher accuracy for evaluating the extent of stress-induced myocardial perfusion abnormalities with coronary angiography as the gold standard. The data were featured today in an oral presentation (# 0917-03) by Jamshid Maddahi, M.D. F.A.C.C., Professor of Molecular and Medical Pharmacology (Nuclear Medicine) and Medicine (Cardiology) at the David Geffen School of Medicine at UCLA, and the Lead Principal Investigator of the study, at the [American College of Cardiology 59th Annual Scientific Session](#) in Atlanta.

“These initial results, in a very small patient population, are encouraging, as they already show significant improvements in diagnostic accuracy using PET imaging with flurpiridaz F 18 as compared to SPECT imaging with Tc-99m for the detection and evaluation of coronary artery disease,” said Dr. Maddahi. “A product that could demonstrate increased diagnostic specificity would provide physicians with a useful tool to reduce the number of false positive results often associated with SPECT imaging, and, therefore reduce the number of unnecessary cardiac catheterizations.”

Nine patients from a single study center underwent same day rest-stress Tc-99m labeled SPECT MPI and separate day rest-stress flurpiridaz F 18 PET MPI and coronary angiography. For each patient, 17 myocardial segments were visually scored for each rest and stress image by independent observers who were blinded to the other results. Summed stress scores, summed rest scores and summed difference scores were determined for each patient from the segmental scores. The percentage of narrowing in each coronary artery was evaluated blindly, and greater than 70 percent luminal diameter narrowing was considered significant.

Findings showed that the overall accuracy for correct identification of diseased coronary arteries was 93 percent (25/27) for PET and 78 percent (21/27) for SPECT. Six patients were found to have CAD with both SPECT and PET, and for the three patients without CAD, all three were found to be normal through PET imaging and two were found to be normal through SPECT. Of the nine diseased coronary arteries, PET detected all and SPECT detected eight. Of the 18 normal coronary arteries, PET imaging identified 16 of the 18 arteries while SPECT found 13 of the 18. Specificity for the right coronary artery was significantly higher through PET imaging compared to SPECT ($p < 0.05$): 100 percent compared to 43 percent.

“These preliminary data for flurpiridaz F 18 PET MPI indicate that more accurate diagnosis of the large segment of coronary artery disease may be possible than with currently available MPI procedures,” said Alex Ehlgen MD, Associate Medical Director, Clinical R&D, Lantheus Medical Imaging, Inc. “PET perfusion imaging continues to be examined as an important advance in myocardial perfusion imaging, and we look forward to Phase 2 study results for this novel agent.”

“Lantheus is fully committed to the ongoing evaluation of flurpiridaz F 18 PET imaging to further understand the diagnostic impact it may have in detecting coronary artery disease, the nation’s leading cause of death,” added Don Kiepert, President and Chief Executive Officer, Lantheus Medical Imaging, Inc. “A new, improved perfusion tracer for use with PET imaging could lead to improved detection and characterization of coronary artery disease, resulting in better patient outcomes.”

About Flurpiridaz F 18

Flurpiridaz F 18, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1), was designed to be a novel myocardial perfusion PET imaging agent for the diagnosis of coronary artery disease (CAD). The agent is currently in Phase 2 clinical trials. CAD is the leading cause of death in the United States for both men and women¹. Each year, more than half a million Americans die from CAD¹.

Phase 1 studies, also led by Dr. Maddahi, indicated that flurpiridaz F 18 is well-tolerated and demonstrates radiation dosimetry that is comparable to, or less than, that of other PET imaging agents. The data also showed high myocardial uptake at rest that significantly increased with pharmacologically induced stress as well as a ratio of myocardial to background uptake that was favorable and improved over time, suggesting strong potential as a myocardial perfusion PET imaging agent for patients both at rest and under stress.

About Positron Emission Tomography

Positron emission tomography, also called PET imaging or a PET scan, is a type of nuclear medicine imaging². PET images provide 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 structure³. PET scanning is useful in evaluating a variety of conditions — including neurological disease, heart disease and cancer³. For myocardial perfusion imaging, SPECT remains the dominant modality at this time; however, there is increasing interest in the use of PET for this purpose⁴. In contrast with SPECT, PET offers higher spatial resolution, greater sensitivity, and accurate, well-validated attenuation correction⁴.

About Myocardial Perfusion Imaging

Myocardial perfusion imaging (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 heart⁵. MPI is used to identify areas of reduced blood flow (perfusion) to the heart muscle⁵. 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 disease⁵.

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, ABLAVARTM (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, TechnoLite® (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.

1National Institutes of Health, National Heart, Lung, and Blood Institute. Coronary Artery Disease: Who Is At Risk.

http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_WhoIsAtRisk.html

2 Radiology Info. What is Positron Emission Tomography – Computed Tomography (PET/CT) Scanning.

<http://www.radiologyinfo.org/en/info.dfm?pg=PET>. Assessed on February 17, 2010.

3National Institutes of Health. NIH Clinical Center. Positron Emission Tomography Department Overview.

<http://clinicalcenter.nih.gov/pet/>

4Glover, David K and Gropler, Robert J. Editorial: Journey to find the ideal PET flow tracer for clinical use: are we there yet? *J Nucl Cardiology* 2007; 15:765-8

5 Society of Nuclear Medicine. Procedure Guidelines for Myocardial Perfusion Imaging. Version 3.0 June 2002

http://interactive.snm.org/docs/pg_ch02_0403.pdf. Assessed on February 18, 2010.