

Lantheus Medical Imaging, Inc. Announces FDA and Health Canada Approval of Australian Nuclear Science and Technology Organisation (ANSTO)-Supplied Key Medical Isotope to Manufacture Technelite® Generator

July 9, 2009 3:54 PM ET

Swift Approvals Underscore Urgency for Reliable Global Access to Isotope Critical For Diagnostic Imaging Tests

N. BILLERICA, Mass. (July 9, 2009) – Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic imaging, today announced that the U.S. Food and Drug Administration (FDA) and Health Canada have approved the Company's supplemental New Drug Application (sNDA) for FDA and Supplemental New Drug Submission (SNDS) for Health Canada to qualify the Australian Nuclear Science and Technology Organisation (ANSTO) as a valid supplier for low-enriched uranium (LEU)-derived molybdenum-99 (Mo-99) in the United States and Canada, respectively. Mo-99 is the parent isotope of technetium-99m (Tc-99m), the most widely used medical radioisotope in the world for molecular and nuclear diagnostic imaging procedures. The approval notifications both from the FDA and from Health Canada were received within a one-week timeframe of Lantheus' filing of the sNDA and SNDS applications, respectively.

With these approvals, Lantheus will become the first domestic company to offer technetium-99m (Tc-99m) using Mo-99 derived from LEU targets to the U.S. and Canada, reinforcing the Company's commitment to ensuring reliable supply and global access to Tc-99m. Lantheus anticipates receiving regular supply from ANSTO within the next several weeks for use in its Technelite® generator line that is currently distributed to the U.S. and Canadian markets. The LEU-derived Mo-99 has been tested and validated by Lantheus for use in its Technelite® generator line to ensure the consistency and reliability that are the hallmarks of the Technelite® brand.

"As a leader in diagnostic imaging, introducing new solutions to ensure supply of medical isotopes is a top priority," said Don Kiepert, president and CEO, Lantheus Medical Imaging, Inc. "The FDA and Health Canada's swift approvals of our sNDA and SNDS qualifying ANSTO to supply LEU-derived Mo-99 for our Technelite® generators signal international recognition of the challenges facing the healthcare industry and patients in need of important diagnostic tests. This approval marks a critical step in our efforts to create a future in which diagnostic testing is rarely delayed or denied because of Mo-99 supply chain issues."

Lantheus has been meeting frequently with government officials in the U.S. and Canada to help develop innovative solutions to the current Mo-99 supply issues in North America and around the world. The FDA's and Health Canada's rapid approvals of ANSTO as a valid supplier of LEU-derived Mo-99 exemplify U.S. and Canadian government responsiveness in the face of these global challenges. These approvals also advance Lantheus' own supply chain diversification strategy to secure validated sources for additional supply of Mo-99.

About LEU-Based Mo-99

Mo-99 is the parent isotope of technetium-99m (Tc-99m), the medical isotope used in approximately 80 percent of all nuclear medicine procedures. Mo-99 is produced by the irradiation of uranium "targets" in a reactor. There are only few major worldwide suppliers of Mo-99, and most use highly-enriched uranium (HEU) targets. A primary objective of the National Nuclear Security Administration's Global Threat Reduction Initiative (GTRI) is to minimize proliferation risks by phasing out the use of HEU in civil commerce. ANSTO is the only global commercial supplier that currently produces Mo-99 using LEU targets, and Lantheus will be the first generator manufacturer to bring this LEU-based Mo-99 to the U.S. and Canadian market.

About Lantheus Medical Imaging, Inc.

Lantheus Medical Imaging, Inc., a worldwide leader in diagnostic medicine for the past 50 years, is committed to advancing and investing in the field of diagnostic imaging. The company's proven success in discovering, developing and marketing innovative medical imaging agents provides a solid platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. The company is home to leading cardiac imaging brands, including Cardiolite® (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection), DEFINITY® Vial For (Perflutren Lipid Microsphere) Injectable Suspension, and Technelite® (Technetium Tc99m Generator) and has nearly 600 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada, and Australia. For more information, visit www.lantheus.com.