Lantheus Announces FDA Grants PDUFA Date for LNTH-2501 (Ga 68 edotreotide), a PET Diagnostic Imaging Kit Targeting Somatostatin Receptor-Positive (SSTR+) Neuroendocrine Tumors (NETs)

Oct 30, 2025

PDUFA Date Set for March 29, 2026

BEDFORD, Mass., Oct. 30, 2025 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the U.S. Food and Drug Administration (FDA) has established a Prescription Drug User Fee Act (PDUFA) date for LNTH-2501 (Gallium-68 edotreotide). LNTH-2501 is a diagnostic kit for the preparation of Ga 68 edotreotide Injection, indicated for use with positron emission tomography (PET) imaging for localization of somatostatin receptor-positive (SSTR+) neuroendocrine tumors (NETs) in adult and pediatric patients.

The FDA has set a PDUFA target action date of March 29, 2026.

“The development of LNTH-2501 underscores our commitment to expanding access to high-quality diagnostic solutions in oncology,” said Brian Markison, CEO, Lantheus. “LNTH-2501 has the potential to provide clinicians a reliable and accessible option for identifying and managing somatostatin receptor-positive neuroendocrine tumors, ultimately supporting more informed treatment decisions and improved patient care.”

LNTH-2501 (Ga-68 edotreotide Injection) further expands Lantheus’ oncology diagnostic portfolio with a PET imaging kit for SSTR+ NETs. Submitted under the FDA’s 505(b)(2) pathway, the filing builds on an extensive evidence base for Ga-68 edotreotide, including multiple published studies. LNTH-2501 is designed to deliver high-quality, reliable and accessible SSTR+ NET imaging.

About Neuroendocrine Tumors (NETs)

Neuroendocrine tumors (NETs) are rare, often slow-growing cancers that can develop throughout the body.[1] A subset known as gastroenteropancreatic NETs (GEP-NETs) affects the digestive system and pancreas and may be functional or non-functional depending on hormone activity. In the U.S., it is estimated that there are over 170,000 people living with NETs, with gastroenteropancreatic NETs (GEP-NETs), which are those NETs arising in the pancreas and digestive system, accounting for 55–70% of cases.[2] Because NETs often grow slowly and cause non-specific symptoms, up to 50% are initially misdiagnosed, leading to delayed detection and treatment.[3]

About LNTH-2501 (Ga 68 edotreotide)

LNTH-2501 (Kit for Preparation of Ga 68 edotreotide Injection), is currently under evaluation by the FDA as a radioactive diagnostic kit indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients. LNTH-2501 is supplied as a 2-vial kit to radiopharmacies which allows for direct preparation of Ga 68 edotreotide injection with the eluate of Gallium from an on-site generator at the radiopharmacy. LNTH-2501 is not currently approved by the FDA and is not yet available for sale in the United States. If approved, LNTH-2501 may complement Lantheus’ therapeutic candidate PNT2003 as part of a theranostic approach, advancing the company’s strategy to deliver integrated diagnostic and therapeutic solutions for patients with cancer.

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada, Germany, Sweden, Switzerland and the United Kingdom, Lantheus has been providing radiopharmaceutical solutions for nearly 70 years. 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, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as "designed,” “growing,” “potential,” “would,” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. 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. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include: (i) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA for LNTH-2501; (ii) our ability to launch LNTH-2501 as a commercial product; (iii) the market receptivity to LNTH-2501 as a radiopharmaceutical diagnostic; (iv) the existence, availability and profile of competing products; (v) the potential of LNTH-2501 to complement Lantheus' therapeutic candidate PNT2003 as part of a theranostic approach; and (ix) the risks and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our most recently filed Annual Report on Form 10-K and Quarterly Reports on Form 10-Q).

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[3] P-136 Survey of Challenges in Access to Diagnostics and Treatment for Neuroendocrine Tumor Patients (SCAN): Early Diagnosis and Treatment Availability. Annals of Oncology. Published July 2020. Accessed May 22, 2025. https://www.annalsofoncology.org/article/S0923-7534(20)39517-X/fulltext



Source: Lantheus Holdings, Inc.