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

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BEDFORD, Mass., March 17, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus” or “Company”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, announced today that the U.S. Food and Drug Administration (FDA) has extended its review of the New Drug Application (NDA) for LNTH-2501 (Gallium 68 edotreotide) by three months to June 29, 2026.

The extension and revised target Prescription Drug User Free Act (PDUFA) goal date of June 29, 2026, will allow the FDA additional time to review and consider further manufacturing related information submitted by Lantheus. This standard review extension is not related to the efficacy or safety data of LNTH-2501.

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.

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 70 years. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements
This press release may contain “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. 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 a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA for LNTH-2501 and 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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