



Lantheus Receives Complete Response Letter from FDA for LNTH-2501 (Ga 68 edotreotide)

Jun 26, 2026

BEDFORD, Mass., June 26, 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 issued a Complete Response Letter (CRL) regarding its New Drug Application (NDA) for LNTH-2501 (Gallium 68 edotreotide), a PET diagnostic imaging kit targeting somatostatin receptor-positive (SSTR+) neuroendocrine tumors (NETs).

The FDA stated that the agency cannot approve the NDA by the Prescription Drug User Fee Act (PDUFA) action date of June 29, 2026, due to unresolved third-party facility manufacturing-related conditions. The third-party facility is responsible for drug product manufacturing. Satisfactory resolution of the unresolved facility inspection-related conditions is required before the LNTH-2501 NDA may be approved.

The CRL did not identify any concerns regarding the data submitted by Lantheus in support of the application, nor did it identify any issues related to the safety or efficacy of LNTH-2501.

"We remain confident in LNTH-2501 and are committed to bringing this imaging agent to NETs patients and healthcare providers as soon as possible," said Mary Anne Heino, Executive Chairperson and Chief Executive Officer, Lantheus. "The feedback received from the FDA relates solely to our third-party manufacturer, and not to the clinical performance of the product. We are working closely with our partner and the Agency to address these facility manufacturing-related conditions and advance the program."

About LNTH-2501 (Ga 68 edotreotide)

LNTH-2501 (Kit for Preparation of Ga 68 edotreotide Injection), is an investigational 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 our ability to work with our third-party manufacturing partner to address the feedback outlined in the CRL in order 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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