Lantheus Receives FDA Tentative Approval for Lutetium Lu 177 Dotatate (PNT2003), Radioequivalent to LUTATHERA®

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BEDFORD, Mass., March 02, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus" or the "Company") (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 it has received U.S. Food and Drug Administration (FDA) tentative approval for the Abbreviated New Drug Application (ANDA) for Lutetium Lu 177 Dotatate (PNT2003), a radioequivalent[1] version of LUTATHERA® (lutetium Lu 177 dotatate). LUTATHERA® is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

"As the first radioequivalent to LUTATHERA to receive FDA tentative approval, PNT2003 marks an important step forward in Lantheus' work to advance treatment options for patients with GEP-NETs. This milestone comes at a time when advances in imaging and evolving clinical guidelines are enabling the identification of more patients who stand to benefit from targeted radiopharmaceutical therapies. As the leading radiopharmaceutical-focused company, we remain committed to meeting this growing demand and look forward to making PNT2003 available to patients pending final FDA approval," said Mary Anne Heino, Chief Executive Officer of Lantheus.

The FDA tentative approval indicates that the FDA has completed its review of the ANDA and that it meets the requirements for approval under the Federal Food, Drug and Cosmetics Act. Full approval of the ANDA is subject to the expiration of the 30-month stay in June 2026, triggered in connection with a Hatch-Waxman patent litigation.

Lantheus licensed exclusive worldwide rights (excluding certain territories) to PNT2003 from POINT Biopharma Global, Inc. in December 2022. To read the press release announcing that licensing transaction, please click here. POINT was acquired by Eli Lilly and Company in December 2023.

About GEP-NETs
Neuroendocrine tumors (NETs) are rare, often slow-growing cancers that can develop throughout the body. 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.[2] Over the last few decades, the incidence of GEP-NETs has increased significantly, with the prevalence in the U.S. estimated to be approximately 200,000 patients.[3] Because GEP-NETs often grow slowly and cause non-specific symptoms, up to 50% are initially misdiagnosed, with patients waiting an average of 4.3 years from symptom onset to diagnosis.[4,5]

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

Safe Harbor for Forward-Looking and Cautionary Statements
This press release contains "forward-looking statements" that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential FDA full approval of PNT2003 and statements regarding Lantheus' expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements may be identified by their use of terms such as "forward," "look" 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.

[1]The term radioequivalent is used to describe a radiopharmaceutical whose mechanism of action is determined to be equivalent to that of the reference product approved by the FDA, or a similar regulator outside of the US.

[2]Neuroendocrine Tumors. Cleveland Clinic. Published June 26, 2024. Accessed May 22, 2025. https://my.clevelandclinic.org/health/diseases/22006-neuroendocrine-tumors-net

[3]Dasari A, Shen C, Halperin D, Zhao B, Zhou S, Xu Y, Shih T, Yao JC. Trends in the Incidence, Prevalence, and Survival Outcomes in Patients With Neuroendocrine Tumors in the United States. JAMA Oncol. 2017 Oct 1;3(10):1335-1342. doi: 10.1001/jamaoncol.2017.0589. PMID: 28448665; PMCID: PMC5824320.

[4]Kolarova T, et.al. P-136 Survey of challenges in access to diagnostics and treatment for neuroendocrine tumor patients (SCAN): Early diagnosis and treatment availability. Annals of Oncology, Volume 31, S134.

[5]Raphael MJ, Chan DL, Law C, Singh S. Principles of diagnosis and management of neuroendocrine tumours. CMAJ. 2017 Mar

13;189(10):E398-E404. doi: 10.1503/cmaj.160771. PMID: 28385820; PMCID: PMC5359105.

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