



Lantheus Receives Final FDA Approval for BRAVNETSA™ (Lutetium Lu 177 Dotatate), the Only Radiopharmaceutical FDA has Determined to be Bioequivalent and Therapeutically Equivalent to LUTATHERA® for the Treatment of GEP-NETs

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Approval of BRAVNETSA expands radioligand treatment options for adult patients with somatostatin receptor-positive (SSTR+) gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

BEDFORD, Mass., Sept. 22, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus" or the "Company") (NASDAQ: LNTX), 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 granted final approval for BRAVNETSA™ (lutetium Lu 177 dotatate), a bioequivalent and therapeutically equivalent radiopharmaceutical to LUTATHERA® (lutetium Lu 177 dotatate). BRAVNETSA is indicated for the treatment of adult patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

"As the only radiopharmaceutical the FDA has determined to be bioequivalent and therapeutically equivalent to LUTATHERA approved in the United States, BRAVNETSA's approval marks an important milestone for Lantheus as we continue to expand our radiopharmaceutical portfolio, bringing additional treatment options to people living with GEP-NETs," said Mary Anne Heino, Executive Chairperson and CEO, Lantheus. "We are focused on a thoughtful launch and ensuring the right commercial and operational capabilities are in place to support reliable supply and broad patient access."

BRAVNETSA was approved through the FDA's Abbreviated New Drug Application (ANDA) pathway. As part of this review, BRAVNETSA is the only radiopharmaceutical the FDA has determined to be bioequivalent and therapeutically equivalent to the reference product, LUTATHERA.

"For more than 70 years, Lantheus has helped define what's possible in radiopharmaceuticals. As the first radioligand therapy approved through the ANDA pathway, BRAVNETSA represents a breakthrough for our industry and opens a new regulatory pathway for innovation," said Ludger Dinkelborg, PhD, Head of Research and Development, Lantheus. "Innovation comes in many forms, and this approval reflects Lantheus' ability to apply our deep radiopharmaceutical expertise in navigating the ANDA process and gives clinicians another FDA-approved option to support treatment decisions based on each patient's needs."

Visit www.BRAVNETSAhcp.com for more information on when the product will be available.

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.¹ 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.² 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.^{3,4}

About BRAVNETSA

BRAVNETSA (lutetium Lu 177 dotatate), previously referred to as PNT2003, is bioequivalent and therapeutically equivalent to LUTATHERA.

INDICATION

BRAVNETSA is indicated for the treatment of adult patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

Pediatric use information is approved for Advanced Accelerator Applications USA INC's LUTATHERA (lutetium Lu 177 dotatate) injection for intravenous use. However, due to Advanced Accelerator Applications USA Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

IMPORTANT SAFETY INFORMATION IN ADULTS

WARNINGS AND PRECAUTIONS

Risk From Radiation Exposure

BRAVNETSA contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer.

Radioactivity may be detected in the urine for up to 30 days following BRAVNETSA administration. Minimize radiation exposure in patients, medical personnel, and household contacts during and after treatment with BRAVNETSA consistent with institutional good radiation safety practices, patient management procedures, Nuclear Regulatory Commission patient release guidance, and provide instructions to the patient for follow-up radiation protection at home.

Myelosuppression

In NETTER-1, myelosuppression occurred more frequently in patients receiving lutetium Lu 177 dotatate injection with long-acting octreotide compared with patients receiving high-dose, long-acting octreotide (all Grades/Grade 3 or 4): anemia (81%/0% vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0%), and neutropenia (26%/3% vs 11%/0%). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to Grade 1, 9 to Grade 2, and 1 to Grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue BRAVNETSA based on the severity of myelosuppression.

Secondary Myelodysplastic Syndrome and Leukemia

In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (sMDS) was reported in 2.3% of patients receiving lutetium Lu 177 dotatate injection with long-acting octreotide compared with no patients receiving high-dose, long-acting octreotide. In ERASMUS, 16 patients (2%) developed sMDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (9 to 45 months) for sMDS and 55 months (32 to 125 months) for acute leukemia.

Renal Toxicity

In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following lutetium Lu 177 dotatate injection. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after BRAVNETSA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and the day after administration of BRAVNETSA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue BRAVNETSA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure.

Hepatotoxicity

In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue BRAVNETSA based on the severity of hepatotoxicity.

Hypersensitivity Reactions

Hypersensitivity reactions, including angioedema, occurred in patients treated with lutetium Lu 177 dotatate injection. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following BRAVNETSA administration for a minimum of 2 hours in a setting where cardiopulmonary resuscitation medication and equipment are available. Discontinue the infusion upon the first observation of any signs or symptoms consistent with a severe hypersensitivity reaction and initiate appropriate therapy. Premedicate patients with a history of Grade 1 or 2 hypersensitivity reactions to BRAVNETSA before subsequent doses. Permanently discontinue BRAVNETSA in patients who experience Grade 3 or 4 hypersensitivity reactions.

Neuroendocrine Hormonal Crisis

Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm, and hypotension, occurred in <1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial lutetium Lu 177 dotatate injection dose. Two patients (<1%) were reported to have hypercalcemia. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction, or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogs, fluids, corticosteroids, and electrolytes as indicated.

Embryo-Fetal Toxicity

BRAVNETSA can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating BRAVNETSA. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BRAVNETSA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BRAVNETSA and for 4 months after the last dose.

Risk of Infertility

BRAVNETSA may cause infertility in males and females. The recommended cumulative dose of 29.6 GBq of BRAVNETSA results in a radiation absorbed dose to the testes and ovaries within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The most common Grades 3-4 adverse reactions ($\geq 4\%$ with a higher incidence in the BRAVNETSA arm) are lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia, and hypokalemia.

DRUG INTERACTIONS

Somatostatin Analogs

Discontinue long-acting somatostatin analogs at least 4 weeks and short-acting octreotide at least 24 hours prior to each BRAVNETSA dose. Administer short- and long-acting octreotide during BRAVNETSA treatment as recommended.

Glucocorticoids

Avoid repeated administration of high doses of glucocorticoids during treatment with BRAVNETSA.

USE IN SPECIFIC POPULATIONS

Advise patients not to breastfeed during BRAVNETSA treatment.

To report SUSPECTED ADVERSE REACTIONS, contact Lantheus at 1-800-362-2668 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for [BRAVNETSA](#).

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" 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 "expected," "only," "positioned," "look forward," 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) our ability to successfully commercialize BRAVNETSA and achieve market adoption; (ii) the ability of our supply and distribution network to manufacture and deliver BRAVNETSA reliably; (iii) the existence, availability and profile of competing products; (iv) the outcome of pending or future litigation; and (v) 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).

References:

¹Neuroendocrine Tumors. Cleveland Clinic. Published June 26, 2024. Accessed May 22, 2025. <https://my.clevelandclinic.org/health/diseases/22006-neuroendocrine-tumors-net>

²Dasari 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.

³Kolarova 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.

⁴Raphael 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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