Lantheus Announces FDA Acceptance of New Drug Application for MK-6240, a PET Imaging Agent Targeting Tau in Alzheimer's Disease

Oct 28, 2025

PDUFA Date Set for August 13, 2026

BEDFORD, Mass., Oct. 28, 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 accepted its New Drug Application (NDA) for MK-6240, the company's investigational F18-labeled tau-targeted Positron Emission Tomography (PET) imaging agent for the detection of tau neurofibrillary tangle (NFT) pathology in patients with cognitive impairment being evaluated for Alzheimer's disease. MK-6240 previously received Fast Track designation from the FDA for its potential to address an unmet medical need in Alzheimer's disease diagnostics. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of August 13, 2026.

"We're pleased the FDA has accepted our Fast Track application for MK-6240, highlighting the urgent need for innovative Alzheimer's diagnostic tools and the potential of MK-6240 to meet that need by enabling direct visualization of tau pathology," said Brian Markison, CEO, Lantheus. "With over 100 disease-modifying therapies in development, including about 30 targeting tau and 40 targeting beta amyloid, imaging plays a critical role in diagnosis and treatment selection. If approved, MK-6240 would complement beta-amyloid PET imaging and emerging blood-based diagnostics, helping guide treatment strategies for providers and patients."

The NDA submission is supported by data from two pivotal Phase 3 clinical trials, which evaluated MK-6240's performance in detecting tau pathology in early Alzheimer's disease. These studies met their co-primary endpoints of sensitivity and specificity to detect tau NFTs.

About Alzheimer's Disease and Dementia
Alzheimer's disease is a degenerative neurological disorder that causes a decline in cognition and function. In the U.S., there are nearly 12 million people living with mild cognitive impairment or Alzheimer's disease. As the population ages, it is likely that the prevalence of this disease will continue to rise and, by 2050, the number of people 65 and older with mild cognitive impairment and Alzheimer's disease may grow to more than 20 million. [1]

Driven by rising prevalence, more treatment options, and expanded PET imaging guidelines, the U.S. Alzheimer's Disease radiodiagnostic market has the potential to reach over 400,000 scans and $1.5 billion by 2030.[2]

About MK-6240
MK-6240 is designed to target aggregated tau protein in the form of neurofibrillary tangles (NFTs), a key hallmark of several neurodegenerative diseases, including Alzheimer's disease. MK-6240 has demonstrated a high affinity for tau and limited off-target binding in both preclinical and clinical studies.[3,4] Acquired by Lantheus in 2023, MK-6240 previously received Fast Track designation and is currently being used in nearly 100 active clinical trials. We anticipate that MK-6240 will support earlier disease detection, patient staging, therapy selection, and monitoring, and may help enable tau to serve as a surrogate endpoint for treatment efficacy.

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 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 MK-6240; (ii) our ability to launch MK-6240 as a commercial product; (iii) the market receptivity to MK-6240 as a radiopharmaceutical diagnostic; (iv) the existence, availability and profile of competing products; (v) our ability to obtain and maintain adequate coding, coverage and payment for MK-6240; (vi) the safety and efficacy of MK-6240; (vii) the intellectual property protection of MK-6240; (viii) our ability to successfully develop and scale the manufacturing capabilities to support the launch of MK-6240; 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).

[1]Alzheimer's Association. 2024 Alzheimer's Disease Facts and Figures. Alzheimer's Dement 2024;20(5).

[2]Addressable market based on current management estimates, internal data, and current WAC / 340B pricing.

[3]Krishnadas N, Doré V, Robertson JS, Ward L, Fowler C, Masters CL, Bourgeat P, Fripp J, Villemagne VL, Rowe CC. Rates of regional tau accumulation in ageing and across the Alzheimer's disease continuum: an AIBL 18F-MK-6240 PET study. EBioMedicine. 2023 Feb;88:104450. doi: 10.1016/j.ebiom.2023.104450. Epub 2023 Jan 27. PMID: 36709581; PMCID: PMC9900352.

[4]Lohith TG, Bennacef I, Vandenberghe R, Vandenbulcke M, Salinas CA, Declercq R, Reynders T, Telan-Choing NF, Riffel K, Celen S, Serdons K, Bormans G, Tsai K, Walji A, Hostetler ED, Evelhoch JL, Van Laere K, Forman M, Stoch A, Sur C, Struyk A. Brain imaging of Alzheimer dementia patients and elderly controls with 18F-MK-6240, a PET tracer targeting neurofibrillary tangles. J Nucl Med. 2019 Jan;60(1):107-114. doi: 10.2967/jnumed.118.208215. Epub 2018 Jun 7. PMID: 29880509.

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