Lantheus Announces Alzheimer's Disease Radiodiagnostic MK-6240 Meets Co-Primary Endpoints in Two Pivotal Studies

Apr 30, 2025

Company plans to file NDA in the third quarter of this year

BEDFORD, Mass., April 30, 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 its clinical-stage F18-labeled tau Positron Emission Tomography (PET) radiodiagnostic, MK-6240 (F18-florquinitau), successfully met its co-primary endpoints in two pivotal studies assessing its sensitivity and specificity. This achievement reinforces the potential of MK-6240 as a valuable diagnostic tool. The data from these two studies will support a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) expected to be filed in the third quarter of 2025.

"As a clinician, the ability to visualize tau pathology represents the opportunity for a seismic shift in how we diagnose and manage Alzheimer's disease," said Luca Passamonti, MD, PhD, Neuroscience Medical Director, Lantheus. "Tools like MK-6240 offer more than just clarity — they provide precision. By identifying tau accumulation early and accurately, we have the potential to improve diagnostic confidence, tailor patient care, and, through monitoring, ultimately change what we know about the trajectory of disease progression. This level of insight has long been missing in the field, and MK-6240, a next-generation imaging agent, has the potential to fill that critical gap."

"The clinical results of MK-6240 underscore our commitment to providing cutting-edge imaging solutions for Alzheimer's disease that align with the latest scientific advancements," said Brian Markison, CEO, Lantheus. "With MK-6240 successfully meeting its primary endpoints in both pivotal studies, we are moving closer to delivering this innovative radiodiagnostic to potentially support precise diagnoses and improve disease management."

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. The successful completion of these studies represents the next step in advancing MK-6240 as a potential tool to aid in the diagnosis, staging, and monitoring of Alzheimer's disease.

The development of MK-6240 complements Lantheus' ß amyloid PET imaging agent, NAV-4694 (F18-flutafuranol), which is currently in Phase 3 development and is actively utilized in both academic and industry-led investigational therapeutic trials for Alzheimer's disease. Together, these imaging agents, if approved, will further position Lantheus as the leader in radiopharmaceutical innovation, supporting the evolving diagnostic landscape for neurodegenerative conditions.

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.[1] It is estimated that there are over 100 therapies in clinical development targeting either beta amyloid or tau.

About Alzheimer's Disease

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 aged 65 and older with mild cognitive impairment and Alzheimer's disease may grow to more than 20 million. [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 has received Fast Track designation and is currently being used in over 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. Lantheus expects to file an NDA with the FDA in the third quarter of 2025.

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 and Sweden, 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 "continue,” “expects,” “may,” “moving closer,” “plans,” “poised,” “position,”“potential,” “will,” 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 RiskFactors section in our most recently filed Annual Report on Form 10-K and Quarterly Reports on Form 10-Q).

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

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

[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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Source: Lantheus Holdings, Inc.