Lantheus Presents Data from Two Pivotal Phase 3 Studies of TAUKLARIFY (Florquinitau F 18 Injection) PET Imaging in Early Alzheimer's Disease

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Results presented at CTAD 2026 demonstrated high sensitivity, specificity and inter-reader agreement across two pivotal Phase 3 studies utilizing a novel prospectively defined clinical radiological reference standard

BEDFORD, Mass., Nov. 16, 2026 (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 results from two pivotal Phase 3 studies evaluating the diagnostic performance of the TAUKLARIFY™ (florquinitau F 18 injection) PET imaging, also referred to as MK-6240, which supported FDA use in adults with cognitive impairment being evaluated for Alzheimer's disease to identify patients with neurofibrillary tangle (NFT) pathology. The safety and effectiveness of TAUKLARIFY have not been established for the evaluation of non-Alzheimer's disease tauopathies. In both studies, which included individuals with early symptomatic disease, all five independent readers met the prespecified co-primary endpoints of sensitivity and specificity, demonstrating consistent diagnostic performance and high inter-reader agreement. Results were presented today at the Clinical Trials on Alzheimer's Disease (CTAD) 2026 meeting in Boston, Massachusetts.

"Tau neurofibrillary tangles are among the pathological features most closely associated with cognitive decline and prognosis in Alzheimer's disease, making their reliable detection especially important in earlier clinical stages," said Christopher Rowe, MD BMBS, FRACP, FAANMS, Director of Molecular Imaging Research at Austin Health and presenting author of the CTAD presentation. "I am encouraged by the strength and consistency of these findings across both Phase 3 studies which clearly show how tau-targeted PET imaging can help identify tau pathology in people with Alzheimer's disease, including those in earlier clinical stages of the disease. These findings may give clinicians a clearer view of disease progression at a time when that information may be particularly valuable."

"What makes these studies particularly noteworthy is the use of a prospectively defined clinical radiological reference standard informed by extensive neuropathological evidence," said Ludger Dinkelborg, PhD, Head of Research & Development at Lantheus. "This innovative approach allowed the inclusion of images from individuals at the early stages of symptomatic Alzheimer's disease, and through a rigorous evaluation, demonstrated that the diagnostic performance of TAUKLARIFY PET scans in this population was highly consistent across two independent pivotal studies. These findings reinforce how tau imaging, alongside amyloid beta imaging, may provide complementary insights that help researchers better characterize Alzheimer's disease and advance hope for physicians and patients fighting against this disease."

The two pivotal studies evaluated 617 TAUKLARIFY PET scans sourced from three established prospective Alzheimer's disease studies. To assess diagnostic performance in individuals with early symptomatic Alzheimer's disease, the studies employed a prospectively defined clinical and radiographical reference standard informed by an extensive neuropathological evidence base. Under this framework, amyloid beta PET-positive individuals with cognitive impairment were classified as having tau pathology, and age-matched amyloid beta-negative cognitively normal individuals were classified as not having tau pathology. Independent reader assessments were compared against this standard.

In each pivotal study, all five independent readers met the prespecified co-primary sensitivity and specificity success criteria. Study success required that at least the same three of five readers achieve a lower bound of the 95% confidence interval greater than 60% for both sensitivity and specificity. In Study CE-20-01, sensitivity across readers ranged from 79.9% to 88.5% and specificity ranged from 97.9% to 99.3%. In Study CE-23-01, sensitivity across readers ranged from 68.2% to 82.4% and specificity ranged from 93.5% to 99.4%. Agreement among readers was high in both studies, with generalized Fleiss' kappa values of 0.92 and 0.86, respectively.

Summary of Pivotal Phase 3 Results

Endpoint	**CE-20-01 (N=279)**	**CE-23-01 (N=338)**
Sensitivity (reader range)	79.9%-88.5%	68.2%-82.4%
Specificity (reader range)	97.9%-99.3%	93.5%-99.4%
Majority-Read Sensitivity	87.8%	78.8%
Majority-Read Specificity	98.6%	99.4%
Positive Predictive Value	98.4%	99.3%
Negative Predictive Value	89.0%	82.3%
Inter-Reader Agreement (Fleiss' k)	0.92	0.86

Safety of florquinitau F 18 was assessed in a pooled analysis of 1,734 participants from U.S. POINTER and AIBL who received at least one dose of florquinitau F 18; the tracer was generally well tolerated. The most commonly reported treatment-emergent adverse events occurring in at least 0.1% of participants were headache (0.7%), nausea (0.2%), dizziness (0.1%), injection site reactions (0.1%) and abdominal discomfort (0.1%).

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 more than 7 million people living with 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 Alzheimer's disease may grow to more than 13 million.[1]

TAUKLARIFY™ Indication
TAUKLARIFY is indicated for positron emission tomography (PET) of the brain in adults with cognitive impairment who are being evaluated for Alzheimer's disease to identify patients with tau neurofibrillary tangle (NFT) pathology.

TAUKLARIFY Limitations of Use
The safety and effectiveness of TAUKLARIFY have not been established for the evaluation of non-Alzheimer's disease tauopathies.

Important Safety Information

Contraindication: None.

Warning and Precautions

Risk of Misdiagnosis in Patients Being Evaluated For Alzheimer's Disease
TAUKLARIFY performance for identifying patients with tau NFT pathology was assessed in subjects who were expected to have predominantly no tau NFT pathology (i.e., cognitively unimpaired and amyloid beta PET-negative) or predominantly clinically significant levels of tau NFT pathology associated with Alzheimer's disease (i.e., cognitively impaired and amyloid beta PET-positive). TAUKLARIFY performance for identifying patients with tau NFT pathology may be lower in patients in earlier stages of the pathological spectrum.

A negative TAUKLARIFY scan does not necessarily exclude the presence of tau NFT pathology, and a positive TAUKLARIFY scan does not necessarily confirm the presence of tau NFT pathology. Consider additional evaluation when clinical uncertainty remains.

Radiation Risk
TAUKLARIFY contributes to a patient's overall long-term cumulative radiation exposure . Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe drug handling to protect patients and health care providers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reaction
The most commonly reported adverse reactions (incidence ≥ 0.1%) were headache, nausea, injection site reactions, dizziness, and abdominal discomfort.

Drug Interactions
CYP1A2 inducers: Avoid use of CYP1A2 inducers, including tobacco smoking, at least 7 days before TAUKLARIFY administration.

Use In Specific Population
Lactation: Temporarily discontinue breastfeeding. A lactating woman should pump and discard breast milk for a minimum of 4 hours after TAUKLARIFY administration.

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

Please see full Prescribing Information for TAUKLARIFY.

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 "believe," "continue," "potential," "growing," "improve," "intends," "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) our ability and the timing to launch TAUKLARIFY as a commercial product; (ii) the market receptivity to TAUKLARIFY as a radiopharmaceutical diagnostic; (iii) the successful development by pharmaceutical companies of disease-modifying treatments for Alzheimer's disease, as well as the inclusion of TAUKLARIFY in the prescribing information or guidelines for such disease-modifying treatments; (iv) the existence, availability and profile of competing products; (v) our ability to obtain and maintain adequate coding, coverage and payment for TAUKLARIFY; (vi) the intellectual property protection of TAUKLARIFY; (vii) our ability to successfully develop and scale the manufacturing capabilities to support the launch of TAUKLARIFY; and (viii) 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:

[1]Alzheimer's Association. 2026 Alzheimer's Disease Facts and Figures. Alzheimer's Dementia 2026.

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