Lantheus Announces FDA Approval of TAUKLARIFY™ (Florquinitau F 18 Injection), an F18-Labeled Tau PET Imaging Agent for Alzheimer's Disease

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BEDFORD, Mass., Aug. 14, 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 U.S. Food and Drug Administration (FDA) approval of TAUKLARIFY™ (florquinitau F 18 injection), also referred to as MK-6240, a radiodiagnostic agent 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 has a limitation of use. The safety and effectiveness of TAUKLARIFY have not been established for the evaluation of non-Alzheimer's disease tauopathies.

"Today's approval of TAUKLARIFY reflects both the increasing importance of tau imaging in Alzheimer's disease assessment and the innovative development program that supported this milestone," said Mary Anne Heino, Executive Chairperson and CEO, Lantheus. "As the field continues to advance, clinicians are seeking a more complete understanding of this disease, with tau PET imaging providing information that complements amyloid PET and other diagnostic tools. We remain committed to advancing research that will further define the role of tau imaging in understanding Alzheimer's disease."

Following approval, Lantheus intends to continue supporting Alzheimer's disease therapeutic programs through its Pharma Solutions business while assessing the appropriate path toward broader commercial availability. Lantheus' approach will remain aligned with the needs of its partners and informed by developments across the Alzheimer's disease treatment landscape.

"For clinicians and researchers, tau PET imaging is an important tool for identifying tau pathology in the brain and advancing our understanding of Alzheimer's disease," said Keith Johnson, Professor of Neurology and Radiology, Massachusetts, General Hospital and Harvard Medical School. "The use of sensitive quantitative tau PET imaging is essential for increasing our understanding of potential disease impacts and moving novel treatments forward."

TAUKLARIFY's approval is supported by two blinded read studies, Study 1 and Study 2, that analyzed TAUKLARIFY PET images from more than 500 subjects who participated in three clinical trials. The clinical trials included individuals with mild cognitive impairment, mild Alzheimer's disease dementia and cognitively unimpaired individuals, enabling evaluation across a broad spectrum of cognitive function, including earlier stages of disease. All subjects received an approximate intravenous dose of 185 MBq (5 mCi) of TAUKLARIFY for tau PET imaging.

In both studies, TAUKLARIFY scans were interpreted by independent readers who underwent training on image interpretation and were blinded to subjects' clinical information and amyloid beta PET results. Scans were classified as positive or negative for tau neurofibrillary tangle (NFT) pathology and compared against a pre-established reference standard based on cognitive status and amyloid beta PET findings.

In Study 1, which analyzed images from 279 subjects, Positive Percent Agreement (PPA) across readers ranged from 80% to 88% (95% CI: 72% to 93%), and Negative Percent Agreement (NPA) ranged from 98% to 99% (95% CI: 94% to 100%). Inter-reader agreement was high, with a generalized Fleiss' kappa of 0.92, with a 95% confidence interval of 0.89 to 0.96. In Study 2, which analyzed images from 338 subjects, PPA across readers ranged from 68% to 82% (95% CI: 61% to 87%), and NPA ranged from 93% to 99% (95% CI: 89% to 100%). Inter-reader agreement was high, with a generalized Fleiss' kappa of 0.86, with a 95% confidence interval of 0.82 to 0.89.

Safety was evaluated in 1,734 subjects. The most commonly reported adverse reactions, with incidence greater than or equal to 0.1%, were headache (0.7%), nausea (0.2%), injection site reactions (0.1%), dizziness (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.

Contacts:

Lantheus
Mark Kinarney
Vice President, Investor Relations
978-671-8842
ir@lantheus.com

Melissa Downs
Executive Director, External Communications
646-975-2533
media@lantheus.com