NEWS RELEASE

Merck Showcases Data for Alzheimer's Disease Candidates MK-2214 and MK-1167 at CTAD 2025

2025-12-01

Merck granted Fast Track Designation by the U.S. FDA for MK-2214 for the treatment of Alzheimer's disease

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced plans to present first-in-human data for MK-2214 and MK-1167 at Clinical Trials on Alzheimer's Disease (CTAD) 2025 in San Diego, California from Dec. 1-4. In addition, the company announced that MK-2214, a novel candidate targeting the abnormal accumulation and aggregation of tau in the brain, has been granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of Alzheimer's disease. Fast Track is a process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and address an unmet medical need.

Key data being presented:

- MK-2214, an investigational novel antibody targeting phosphorylated serine 413 (pS413) tau: First presentation of data from three Phase 1 studies evaluating MK-2214. Two studies assessed the safety, tolerability and pharmacokinetics of a single ascending dose of MK-2214 in healthy volunteers, while a third assessed the safety, tolerability and pharmacokinetics of a multiple ascending dose regimen in individuals with mild cognitive impairment and mild-to-moderate Alzheimer's disease. The results from these studies helped inform an ongoing Phase 2 trial of MK-2214 evaluating safety and efficacy, including its effect on certain changes in the brains of people with early Alzheimer's disease (**NCT07033494**).
- MK-1167, an investigational oral positive allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine

receptor: First presentation of data from a Phase 1 first-in-human study evaluating MK-1167. The trial assessed the effect of single doses of MK-1167 on glutamate metabolism in the prefrontal cortex of healthy adult male volunteers, as measured by 13C-magnetic resonance spectroscopy. The results from this study helped inform dose selection for an ongoing Phase 2 trial of MK-1167 evaluating safety and efficacy, including its effect on memory and mental activity, in people with mild-to-moderate Alzheimer's disease dementia taking stable donepezil treatment (**NCT06721156**).

“Alzheimer’s disease remains one of the greatest neurological challenges of our time and yet new insights are providing important new paths to evaluate potential new therapeutic approaches,” said Dr. Mike Egan, vice president, neuroscience, global clinical development, Merck Research Laboratories. “We are pleased to share data showing progress in our pipeline of candidates targeting Alzheimer’s disease at CTAD 2025.”

Details on Merck abstracts at CTAD 2025:

Abstract number and title	Date and time
P112: Phase 1 studies of MK-2214, a novel antibody targeting pS413 tau, for the treatment of Alzheimer’s disease.	Poster session Monday, December 1, 2025 (3:00 P.M. PST) - Tuesday, December 2, 2025 (5:30 P.M. PST)
P249: MK-1167, a positive allosteric modulator of α7 nicotinic cholinergic receptors: proof-of-biology, dose selection, and clinical trial design.	Poster session Wednesday, December 3, 2025 (7:15 A.M. - 5:30 P.M. PST)

MK-2214 is being developed through an agreement with Teijin Pharma.

About Alzheimer’s disease

Alzheimer’s disease is a progressive brain disorder and the most common cause of dementia, in which people lose memory, thinking skills and the ability to live independently. Alzheimer’s disease affects approximately seven million people in the U.S., with this number estimated to grow to 14 million by 2060. Recent progress in the area of human genetics in addition to advanced technology and screening tools is helping us better understand pathology in the brain and fueling innovative research in Alzheimer’s.

Merck in Neuroscience

At Merck, we are committed to discovering and developing novel therapeutics for a variety of diseases involving the nervous system, which remain among today’s most significant medical challenges. Our research is focused on investigating the complexities of central and peripheral nervous system disorders to treat, slow progression or prevent disease.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the

power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit **www.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2024 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Media Contacts:

Julie Cunningham
(617) 519-6264

Katie Fey
(929) 738-2078

Investor Contacts:

Peter Dannenbaum
(732) 594-1579

Steven Graziano
(732) 594-1583

Source: Merck Sharp & Dohme