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Actinogen Reports Mixed XanaMIA Results in Alzheimer's Trial

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Actinogen's Xanamem showed 30% slowing of Alzheimer's progression in patients over 75, but failed to meet the primary endpoint in XanaMIA.

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Actinogen Medical reported mixed topline results from its pivotal XanaMIA Phase 2b/3 trial of oral emestedastat (Xanamem) in mild to moderate Alzheimer's disease. Although the 10 mg once-daily treatment failed to demonstrate statistically significant superiority over placebo in the overall population, a prespecified analysis showed improved disease stabilization rates in patients older than 75 years.

The 36-week, randomized (1:1), double-blind, placebo-controlled trial enrolled 247 patients across Australia and the US with mild to moderate Alzheimer's disease (AD) and elevated blood levels of phosphorylated tau 181 (pTau181), a biomarker associated with Alzheimer's pathology.

Xanamem demonstrates disease stabilization signal in older patients

In a prespecified analysis of participants older than the median age of 75 years, Xanamem significantly improved the proportion of patients experiencing stable, non-progressive disease compared with placebo.

At Week 36, 40% of participants receiving Xanamem achieved zero progression on the Clinical Dementia Rating Scale–Sum of Boxes (CDR-SB), compared with 22% in the placebo group (*p=0.02*). This represented an 18-percentage-point difference in disease stabilization rates.

The analysis also indicated a 30% slowing of disease progression, based on a mean 0.39-point advantage in CDR-SB scores over placebo at Week 36. However, this difference did not reach statistical significance (*p=0.22)*.

Actinogen attributed the age-related efficacy signal, in part, to increased expression of 11β-hydroxysteroid dehydrogenase type 1 (11β-HSD1) the tissue cortisol synthesis enzyme targeted by Xanamem with advancing age. The company noted that the estimated 30% slowing was comparable to efficacy claims associated with approved anti-amyloid Alzheimer's therapies donanemab and lecanemab. However, cross-trial comparisons require caution because of differences in trial populations, endpoints, and study designs.

Overall population fails to meet primary endpoint

Despite the findings in older participants, Xanamem did not demonstrate statistically significant superiority over placebo on the primary endpoint in the overall study population.

The primary endpoint assessed delayed disease progression using CDR-SB measurements at Weeks 12, 24, and 36. At Week 36, patients receiving Xanamem showed a mean 0.10-point advantage over placebo ($p=0.65$), indicating no statistically significant treatment benefit.

The company also reported small, non-significant numerical trends favouring Xanamem across key secondary endpoints assessing cognition and activities of daily living. These findings do not establish a clinically meaningful benefit in the overall population.

Safety profile maintained over 36 weeks

Xanamem 10 mg daily maintained the favourable safety profile previously established in studies up to 12 weeks across the full 36-week treatment period, with no serious adverse events attributed to the drug.

The company also highlighted its previous safety experience involving more than 500 participants across eight clinical trials and the treatment's oral administration. Its lack of drug-drug interaction potential could be relevant to older patients with Alzheimer's disease, who frequently receive multiple medications, including acetylcholinesterase inhibitors such as donepezil.

FDA discussions and partnering opportunities ahead

Commenting on the findings, Actinogen CEO Dr Steven Gourlay said the company remained confident in Xanamem's risk-benefit profile and would further evaluate the results in older patients, a large population with substantial unmet treatment needs.

The company plans to engage potential development partners and the US Food and Drug Administration (FDA) over the coming months to determine the next development pathway for Xanamem, with particular attention to the older Alzheimer's population. An open-label extension phase of the trial also remains ongoing.

Further trial findings are expected to be presented at a future scientific meeting.

The results present a mixed development picture for Xanamem. While the overall population analysis failed to establish efficacy against the primary endpoint, the statistically significant disease stabilization finding in older participants provides a potential direction for further investigation. Whether this subgroup signal can support a targeted development strategy will depend on additional analyses, regulatory discussions, and confirmation in subsequent clinical studies.

Reference

Actinogen pivotal Alzheimer's disease trial demonstrates clinical benefit in older patients with mild to moderate disease, favorable safety profile and trends towards benefit in the overall population, Actinogen via GlobeNewswire, 19 November 2026

Effect of 10 mg Xanamem on Dementia Due to Alzheimer's Disease (XanaMIA), ClinicalTrials.gov ID NCT06125951



About the Writer

***Mayuri Vaja** (Linkedin) is a Pharm.D professional with a strong interest in clinical research, pharmacovigilance, and medical writing, supported by certifications in pharmacovigilance and academic projects exploring AI in healthcare and drug safety. With a growing focus on evidence-based healthcare and scientific communication, she is developing expertise in clinical research and translating healthcare evidence into clear, meaningful content.*

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