Galimedix THERAPEUTICS

Press Release

DECEMBER 4, 2025

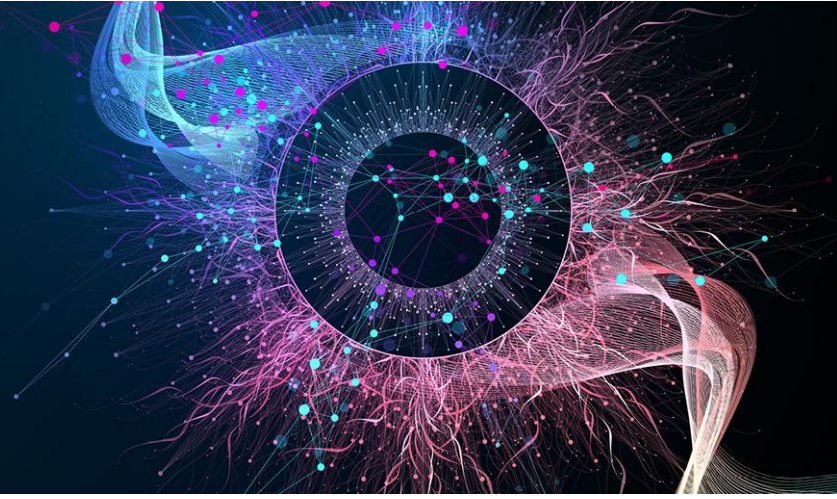
Galimedix Therapeutics presents compelling Phase 1 study results showing excellent safety and pharmacokinetics with oral small molecule GAL-101 at CTAD 2025

- GAL-101 was safe and well tolerated, with no dose-limiting adverse events observed
- Pharmacologically relevant GAL-101 concentrations were detected in cerebrospinal fluid (CSF), confirming blood-brain barrier penetration
- Phase 2 proof-of-concept study in Alzheimer's disease is planned

Kensington, MD, USA and Munich/Martinsried, Germany, December 4, 2025 – Galimedix Therapeutics, Inc. (Galimedix), a Phase 2 clinical-stage biotechnology company developing novel oral and topical neuroprotective therapies with the potential to revolutionize the treatment of serious brain and retinal diseases, presented further data from its Phase 1 study with orally administered GAL-101, a small molecule specifically designed to target misfolded amyloid beta (Aβ) monomers, thereby preventing the formation of soluble, toxic aggregates (Aβ oligomers and protofibrils) present in the brains of patients with Alzheimer's disease (AD). The data were presented at the 18th Clinical Trials on Alzheimer's Disease (CTAD) Conference, held in San Diego, California, USA, December 1-4, 2025.

The presentation, "Oral GAL-101 Demonstrates Excellent Tolerability and Favorable Pharmacokinetics in Phase 1, Paving the Way for Phase 2 Development", highlighted results from the randomized, double-blind Phase 1 study involving approximately 100 healthy volunteers. GAL-101 showed a favorable safety and tolerability profile at all investigated single and multiple ascending (SAD and MAD) doses and under all investigated conditions. Lumbar CSF concentrations measured after multiple dose treatment confirmed that GAL-101 effectively crosses the blood-brain barrier and support once daily dosing for future clinical trials.

"We are pleased to see such favorable pharmacokinetic results from our first-in-human trial with the oral formulation of lead compound, GAL-101," said **Hermann Russ, MD, PhD, Co-founder and Chief Scientific Officer of Galimedix**. "The trial results showed that this novel small molecule was safe and well tolerated and effectively crossed the blood-brain barrier. Based on these clinical results, and the robust pre-clinical data package, we are now planning a Phase 2 proof-of-concept study in Alzheimer's disease. We believe that GAL-101 tablets have the potential to one day become standard of care for all stages of Alzheimer's disease, and we are excited to move forward in development."



No dose-limiting adverse events were observed; all dose levels were well tolerated. GAL-101 was quickly absorbed, and plasma levels were significantly higher than the levels expected to be necessary for clinical efficacy. There was no accumulation of the drug after multiple administrations, and no relevant food effect was observed. Elderly subjects (>65 years) experienced a slightly higher exposure than younger subjects and tolerated the drug equally well.

A Phase 2 study is being planned and will include cognitive functional endpoints and incorporate plasma and CSF biomarkers. Continuous cognitive at-home monitoring is planned to capture any early cognitive functional improvement, which is expected due to the rapid inactivation of toxic Aβ species by GAL-101 observed in pre-clinical testing.

The slides can be accessed here: Stopping Neurodegeneration at its Source with GAL-101

About GAL-101

GAL-101 is a small molecule targeting misfolded amyloid beta (Aβ) monomers and thus preventing the formation of toxic Aβ oligomers and protofibrils. It is being developed in both oral and topical (eyedrops) formulations. Many studies have indicated that these Aβ aggregates are a major underlying cause of neurodegenerative diseases of the brain and retina, and recent approvals of anti-Aβ drugs have also validated them as a key target in Alzheimer's disease. GAL-101 is being developed for the treatment of Alzheimer's disease, dry age-related macular degeneration (dAMD) and glaucoma.

In pre-clinical testing, the compound has been shown to prevent and eliminate all forms of toxic Aβ species while leaving healthy Aβ forms intact. GAL-101 has also demonstrated the potential for neuroprotection and for symptomatic alleviation in pre-clinical models of Alzheimer's disease. Additionally, orally available GAL-101 has shown no antibody-specific immunological side effects (e.g., ARIA), very low systemic toxicity, robust storage stability, and easy and inexpensive manufacturing. Strong efficacy has also been demonstrated in relevant ophthalmic pre-clinical models, protecting neuronal retinal cells from toxic damage. In a previous Phase 1 study, GAL-101 eyedrops demonstrated an excellent safety and tolerability profile. The eDREAM Phase 2 study (NCT06659549) in dAMD/geographic atrophy with GAL-101 eyedrops is ongoing.

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About Galimedix Therapeutics, Inc.

Galimedix is a Phase 2 clinical-stage private company developing novel oral and topical neuroprotective therapies with the potential to revolutionize the treatment of serious brain and retinal diseases. Founded by a seasoned and highly dedicated team of bio-entrepreneurs, pharmaceutical executives and scientists, Galimedix's groundbreaking small molecules offer the hope of changing the course of disease where amyloid beta (Aβ) plays a role, such as in Alzheimer's disease, dry age-related macular degeneration (dAMD) and glaucoma - Galimedix's initial areas of focus.

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