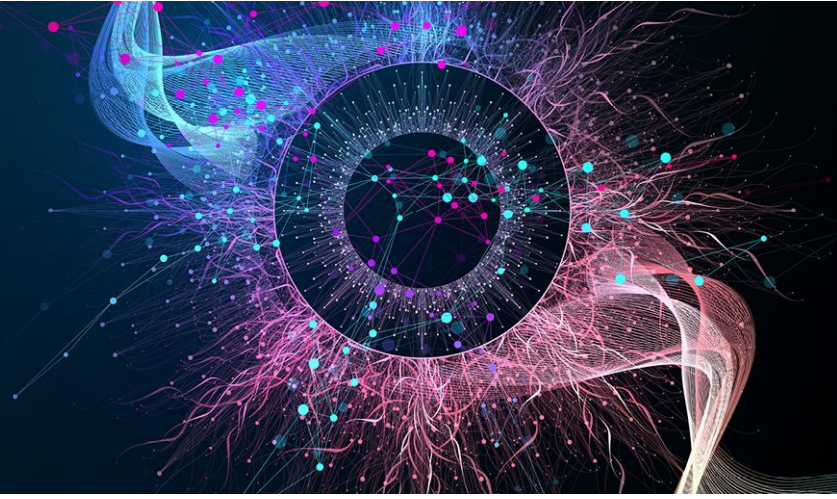
Galimedix THERAPEUTICS

Press Release

05. December 2024



Galimedix Therapeutics initiates Phase 1 study with oral small molecule, GAL-101, an amyloid beta (Aβ) aggregation modulator

- Study to evaluate safety, tolerability and pharmacokinetics of single and multiple ascending oral doses of GAL-101 in healthy volunteers
- Planned indications include Alzheimer's disease, dry AMD and glaucoma
- Phase 2 study with GAL-101 eyedrops in dry AMD expected to start soon

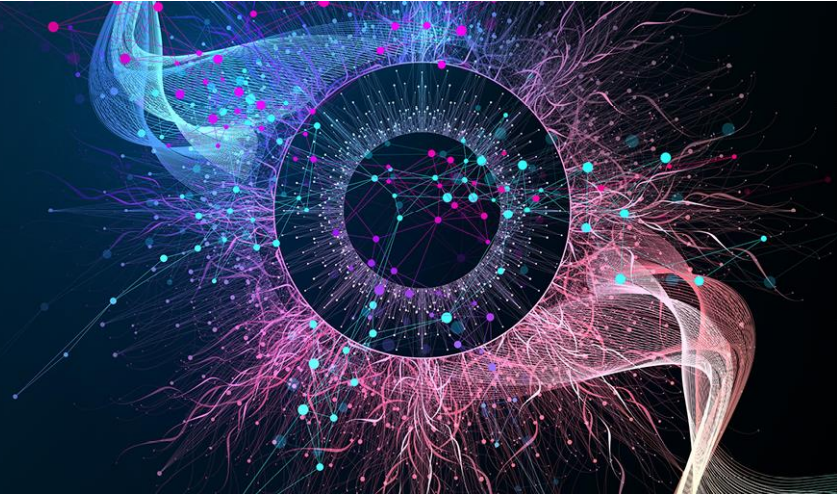
Kensington, MD, USA, December 5, 2024 – Galimedix Therapeutics, Inc. ("Galimedix"), a Phase 2 clinical-stage biotechnology company developing novel oral and topical neuroprotective therapies with the potential to revolutionize the treatment of serious eye and brain diseases, today announced that the first healthy volunteers have been dosed in its Phase 1 study with oral GAL-101, an amyloid beta (Aβ) aggregation modulator. The study is designed to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of orally administered GAL-101.

"We are excited to enter clinical development with the oral formulation of our lead compound, GAL-101. GAL-101 eyedrops have already shown an excellent safety and tolerability profile in early clinical testing, and compelling efficacy with GAL-101 has been demonstrated in relevant ophthalmic and Alzheimer's pre-clinical models," said **Alexander Gebauer, MD, PhD,** Co-Founder and Executive Chairman of Galimedix Therapeutics. "We look forward to seeing the first results from this Phase 1 trial soon, which will guide our oral clinical development program for the treatment of Alzheimer's disease, as well as additional studies in dry age-related macular degeneration and glaucoma."

The Phase 1 study is planned to enroll up to 40 healthy volunteers in the single ascending dose (SAD) part of the trial and 32 subjects in the multiple ascending dose (MAD) part. The study also will evaluate GAL-101's ability to cross the blood-brain barrier, as well as a variety of other parameters. In total, the trial is planned to enroll up to 120 subjects.

About GAL-101

GAL-101 is a small molecule targeting misfolded 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 eye,



and recent approvals of anti-Aβ drugs also have validated them as a key target in Alzheimer's disease. GAL-101 is being developed for the treatment of dry AMD, glaucoma and Alzheimer's disease.

In a previous Phase 1 study, GAL-101 eyedrops demonstrated an excellent safety and tolerability profile. 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 also has been demonstrated in relevant ophthalmic pre-clinical models, protecting neuronal retinal cells from toxic damage. Recruitment of the first patients into a pivotal Phase 2 study (NCT06659549) in dry AMD with GAL-101 eyedrops is expected soon.

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 eye and brain 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 dry AMD, glaucoma and Alzheimer's disease - Galimedix's areas of focus.

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