

# AZTherapies

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## **AZTherapies Completes Enrollment in COGNITE Pivotal Phase 3 Trial of ALZT-OP1 for the Treatment of Early Alzheimer's Disease**

*First-in-class candidate targets microglia to slow or halt neuroinflammation and disease progression*

*ALZT-OP1 trial being conducted under an SPA with expected completion in late 2020*

**BOSTON, Mass., August 1, 2019** – [AZTherapies, Inc.](http://AZTherapies.Inc.), a biopharmaceutical company developing therapeutics to extend brain health, today announced that it has completed target enrollment in its COGNITE Phase 3 clinical trial, evaluating the safety and efficacy of ALZT-OP1 for the treatment of early Alzheimer's disease. The enrolled population of 620 patients follows the screening of approximately 1,800 patients to ensure homogeneous staging of early Alzheimer's patients in the clinical trial.

"ALZT-OP1 uses a novel multi-modal approach that includes attacking the neuroinflammation that leads to neuronal death," said David R. Elmaleh, Ph.D., Founder, CEO, and Chairman of AZTherapies. "By attempting to enhance the brain's microglial immune cells' neuroprotective activity and inhibit pro-inflammatory cytokine production, we aim to halt or slow the progression of Alzheimer's disease in its early stages. ALZT-OP1 is a proprietary combination of two previously approved small molecules that have been re-engineered to provide a daily dose to suppress the brain's neuroinflammatory response. With the COGNITE trial now fully enrolled, we are one step closer to providing Alzheimer's patients with new hope for a treatment and look forward to completing the trial in late 2020."

The COGNITE Phase 3 clinical trial is a global, randomized, placebo-controlled study of 620 patients with early stage Alzheimer's disease, aged 55-79. Patients were identified using cognition, function, and biomarker levels in the cerebrospinal fluid (CSF). The primary endpoint of the study is the change from baseline in Clinical Dementia Rating-Sum Boxes (CDR-SB) at week 72. The trial is being conducted under a special protocol assessment (SPA) agreement with the U.S. Food and Drug Administration.

"I am encouraged by the continued progress in this clinical trial," said Martin Farlow, MD, Professor Emeritus of Neurology at Indiana University School of Medicine, member of the AZTherapies Scientific Advisory Board, and a practicing neurologist. "This trial encompasses a number of unique features, including the narrow age spread of patients, the early stage of disease, and the battery of cognition, function, and the CSF measures included, which may shed light on disease progression. A positive outcome in this study could be a meaningful breakthrough in the treatment of early Alzheimer's disease, validating the role that neuroinflammation plays in neurodegeneration and positioning ALZT-OP1 as a promising new option for the millions of people living with Alzheimer's disease."

**About AZTherapies**

AZTherapies is an advanced clinical-stage biopharmaceutical company developing novel therapies that aim to fundamentally change neurodegenerative disease progression, extending normal cognition and function and improving quality of life in the aging population. Advancing a growing pipeline of candidates to treat patients with few therapeutic options, our lead program, ALZT-OP1, is built on a multi-modal approach that recognizes neuroinflammation as a root cause of serious neurodegeneration and seeks to stop or slow the progression of disease. Our Phase 3 COGNITE trial in early Alzheimer's disease is now fully enrolled and expected to complete in late 2020. Following our lead program, we are advancing candidates for the treatment of post-ischemic stroke cognitive impairment, amyotrophic lateral sclerosis (ALS), and other indications. AZTherapies is a private company headquartered in Boston, Massachusetts. To learn more, please visit [www.aztherapies.com](http://www.aztherapies.com).

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