



Media Contact:

Jennifer LaVin

jlavin@aztherapies.com

Investor Contact:

Brian Bartlett

Chief Financial & Accounting Officer

brian.bartlett@aztherapies.com

**AZTherapies Doses First Patient in Phase 2a Study of ALZT-OP1a in
Amyotrophic Lateral Sclerosis (ALS)**

*Randomized, open-label, multi-center, dose optimization study expected to evaluate
80 patients with mild- to moderate-stage ALS*

BOSTON, Mass., September 9, 2020 – [AZTherapies, Inc.](http://AZTherapies.com), a biopharmaceutical company in advanced clinical trials to treat neuroinflammatory diseases, today announced the dosing of the first patient in its Phase 2a clinical trial examining the safety and efficacy of ALZT-OP1a in patients with mild- to moderate-stage Amyotrophic Lateral Sclerosis (ALS). ALZT-OP1a is the company's proprietary inhaled formulation of cromolyn, engineered to improve blood brain barrier permeability and bioavailability; ALZT-OP1a is also currently being evaluated as part of a combination therapy in a fully enrolled Phase 3 pivotal trial in patients with early stage Alzheimer's disease.

"With a strong unmet medical need and mounting evidence that neuroinflammatory processes are implicated in the initiation and progression of ALS, we are excited to explore the use of ALZT-OP1a in ALS patients for the first time," said David R. Elmaleh, Ph.D., AZTherapies' Founder, CEO, and Chairman. "We have been able to progress this program rapidly from bench to bedside based on comprehensive pre-clinical work and are optimistic that we will see clear safety and efficacy signals from this clinical trial. We believe this is not only a significant step forward for us, but, more importantly, for the many ALS patients with so few treatment options."

Previously conducted work on ALZT-OP1a in the laboratories of Drs. Ghazaleh Sadri-Vikili and Rudolph Tanzi at Massachusetts General Hospital revealed promising data in a SOD-1 mouse model of ALS. Dr. Tanzi, who is Vice Chair of Neurology, Director of the Genetics and Aging Research Unit, Co-Director of the Henry and Allison McCance Center for Brain Health, and Co-Director of the MassGeneral Institute for Neurodegenerative Disease, commented on today's news: "In our pre-clinical evaluations, ALZT-OP1a demonstrated the ability to delay disease onset and progress, reduce motor deficits, and reduce pro-inflammatory cytokine/chemokine levels in the spinal cord and plasma of mice. I will be following the progress of this trial with great interest." Dr. Tanzi is also Joseph P. and Rose F. Kennedy Professor of Neurology at Harvard Medical School and serves as Chair of the AZTherapies Scientific Advisory Board.

The company-sponsored trial, AZT-006 ([NCT04428775](https://clinicaltrials.gov/ct2/show/study/NCT04428775)), is expected to enroll 80 patients at up to 20 centers across the U.S. It is a randomized, open-label study evaluating two doses of ALZT-OP1a administered twice daily via inhalation and is assessing the impact on neuroinflammation by measuring both plasma biomarkers and functional changes using the ALS Functioning Rating Scale-Revised (ALSFRS-R) over a 12-week treatment period. The study is also intended to determine the optimal dose of ALZT-OP1a to be used in further clinical studies in ALS patients. Adult patients aged 18-75 years diagnosed with mild to moderate non-bulbar ALS are eligible to participate.

“We are excited to be participating in this trial and giving hope to ALS patients with a potential new treatment,” said James Caress, M.D., Professor of Neurology, Director, Wake Forest Health Sciences ALS Center, and a Principal Investigator. “As a cytokine release modifier, we believe ALZT-OP1a could slow the development of this progressive neurodegenerative disease, which affects nerve cells in the brain and spinal cord resulting in loss of motor function. Controlling neuroinflammation is an important piece in the ALS treatment puzzle and I am hopeful that the broad spectrum of anti-inflammation activity expected from ALZT-OP1a administration will prove to be of benefit to my patients.”

About AZTherapies

AZTherapies is an advanced clinical-stage biopharmaceutical company developing novel small molecules and biologic therapies that aim to fundamentally change neurodegenerative disease progression, extending normal cognition and function and improving quality of life in the aging population. Our lead candidate, 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; the ALZT-OP1 Phase 3 COGNITE trial in early Alzheimer’s disease is fully enrolled, with trial completion expected in late 2020 and results in the first quarter of 2021. Following our lead program, we are advancing candidates for the treatment of amyotrophic lateral sclerosis (ALS), post-ischemic stroke cognitive impairment, and are pursuing an innovative CAR-Treg program that could have broad application across a spectrum of neurodegenerative diseases. AZTherapies is a private company headquartered in Boston, Massachusetts. To learn more, please visit www.aztherapies.com.

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