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AZTherapies Completes COGNITE Phase 3 Alzheimer's Clinical Trial; Top-Line Data Readout Expected in First Quarter of 2021

Last Patient/Last Visit completed on November 13th enabling full clinical database lock

BOSTON, Mass., November 18, 2020 – AZTherapies, Inc., a biopharmaceutical company in advanced clinical trials to treat neuroinflammatory diseases, today announced the completion of the last patient/last visit in its COGNITE Phase 3 clinical trial, which is evaluating the safety and efficacy of ALZT-OP1, an investigational combination treatment for patients with early stage Alzheimer's disease. Unique in its design, the 72-week clinical trial enrolled more than 600 patients and was conducted under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration.

"With patient evaluations now complete in our ALZT-OP1 Phase 3 clinical trial, we will soon begin data analysis, bringing us one step closer to validating our hypothesis that targeting neuroinflammation could be the key to modifying disease progression – stopping or slowing the advance of early stage Alzheimer's disease," said David R. Elmaleh, PhD, Scientific Founder, Executive Chairman, and Chief Scientific Officer of AZTherapies. "We expect to announce the COGNITE top-line clinical results in the first quarter of 2021. Notably, the COGNITE trial also includes a landmark cerebrospinal fluid biomarker component that should allow for future exploration of correlations between biomarkers and clinical response. As we eagerly anticipate the results, we would like to take this opportunity to thank all of our investigators, our clinical teams, and, most importantly, the patients and families who participated in this important clinical trial."

Our Focus on Alzheimer's Disease
The magnitude of the Alzheimer's disease crisis is well documented, with nearly 6 million Americans currently living with the disease and more than 35 million worldwide affected. The cost to the U.S. healthcare system is estimated to be nearly $300 billion, expected to exceed $1.0 trillion by the year 2050. It is also estimated that the ability to diagnose and treat Alzheimer's early and accurately could save as much as $8.0 trillion in future medical care and costs. Alzheimer's disease is known to involve a number of biological functions in its pathogenesis. While unsuccessful efforts to develop treatments have been principally focused on preventing the formation of amyloid-beta and/or dissolving amyloid plaques (long thought to be the primary cause of disease), research has now turned to alternative methods, including inhibiting neuroinflammatory pathways in early stage Alzheimer's patients.

About ALZT-OP1 and the Phase 3 COGNITE Trial

Building on the hypothesis that targeting neuroinflammation using a multi-modal approach could be key to fighting neurodegenerative disease, we have developed ALZT-OP1, a proprietary combination of two previously approved small molecules that have been re-engineered, reformulated, and optimized to enable rapid pulmonary uptake and crossing of the blood-brain barrier. In doing so, ALZT-OP1 aims to shift activated microglia from a pro-inflammatory state to a neuroprotective state, thus reducing neuroinflammation. If successfully developed, we intend to file for regulatory approval in the U.S. under the 505(b)2 streamlined U.S. Food and Drug Administration (FDA) approval process.

The COGNITE Phase 3 clinical trial (NCT02547818) is a global, randomized, placebo-controlled trial evaluating the safety and efficacy of ALZT-OP1 in patients with early Alzheimer's disease. More than 600 patients enrolled in the study, which consists of four arms: one evaluating the combination of proprietary formulations of inhaled ultra-micronized cromolyn (ALZT-OP1a) and oral ibuprofen (ALZT-OP1b), one each evaluating ALZT-OP1a and ALZT-OP1b alone, and one placebo arm. Patients' initial stage of Alzheimer's disease was measured by the Clinical Dementia Rating (CDR) scale and the level of a key biomarker. With a primary endpoint of mean change from baseline in Clinical Dementia Rating-Sum of Boxes (CDR-SB) at week 72, the protocol was conducted under a Special Protocol Assessment (SPA) with the FDA.

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 now complete, with top-line clinical results expected in the first quarter of 2021. Following our lead program, we are currently advancing a candidate for the treatment of amyotrophic lateral sclerosis (ALS) through a Phase 2a clinical trial and exploring that same candidate's potential in the treatment of post-ischemic stroke cognitive impairment. We are also progressing a next-generation oral formulation of ALZT-OP1 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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