

Cognition Therapeutics Receives \$75.8 Million NIA Grant for 540-Patient Phase 2 Study of CT1812 in Collaboration with the Alzheimer's Clinical Trials Consortium

June 8, 2020

New York, June 8, 2020 — Cognition Therapeutics, Inc., a clinical stage neuroscience company focused on the protection and restoration of synaptic function in Alzheimer's disease and other neurodegenerative disorders, today announced that the National Institute on Aging (NIA) of the National Institutes of Health (NIH) has awarded the Company a grant (number R01AG065248) expected to total \$75.8 million over five years to support a 540-patient Phase 2 study of CT1812 in individuals with early Alzheimer's disease. The study will be conducted in conjunction with the [Alzheimer's Clinical Trials Consortium \(ACTC\)](#), an NIH-funded clinical trial network of 35 leading academic sites with expertise in clinical trials in Alzheimer's disease.

[Lisa Ricciardi](#), chief executive officer of Cognition Therapeutics, stated, "It is gratifying and humbling to have received a grant award from the NIA of such magnitude, and it comes with an equally significant sense of responsibility. We look forward to moving the study process forward with our new partners at ACTC."

Proposals to NIA for ACTC projects are highly competitive due in part to the ACTC's limit of five-to-seven trials during any five-year award period as well as the NIA's funding obligations outside of ACTC projects. Cognition began the rigorous application and review process for this study in mid-2019 and are now working with our collaborators at ACTC to educate member sites in preparation for beginning patient recruitment. Paul Aisen, M.D., director of the Alzheimer's Therapeutic Research Institute (ATRI) of the Keck School of Medicine at USC and a founding leader of the ACTC will serve as project director. Susan Catalano, Ph.D., co-founder and chief science officer of Cognition Therapeutics and Christopher van Dyck, M.D., director of the Yale Alzheimer's Disease Research Center, will serve as co-primary investigators.

[CT1812](#) is a brain-penetrant small-molecule drug that has been shown to target the sigma-2 receptor, a key regulator of the cellular damage response. By so doing, CT1812 displaces toxic A β oligomers from synapses and protects against further oligomer binding, potentially stopping the synapse damage and destruction that is characteristic of neurodegenerative diseases such as Alzheimer's.

"Evidence suggests that A β oligomers exert their toxic effects on synapses long before symptoms of Alzheimer's become apparent," stated [Dr. Catalano](#). "Because CT1812 is designed to prevent A β oligomers from binding to synapses, it may have utility in a broad range of Alzheimer's patients including those who are early in their disease progression. We look forward to exploring this potential with our esteemed colleagues at the ACTC."

"Given our work at Yale in measuring synapses in vivo using PET imaging, we have been focused on the potential of CT1812 to preserve or even restore synapses," stated Dr. van Dyck. "I'm looking forward to continuing our work together on this Phase 2 study to help determine the full potential of CT1812."

The study is expected to enroll approximately 540 individuals with mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease (MMSE 20-30) who have elevated A β (as measured by PET or CSF). Participants will be randomized to receive CT1812 or placebo for 18 months. In addition to a battery of cognitive measures, the study will use a variety of biomarkers to measure target engagement and assess changes in neurodegeneration and disease progression.

"This study presented an excellent opportunity for the ACTC to leverage our sizable and experienced community of Alzheimer's trial sites to investigate the potential that CT1812 may have to preserve cognitive function for individuals at early stages of Alzheimer's disease," added Dr. Aisen. "We are grateful to NIA for their continued support of the ACTC and for their significant support of this study in particular."

About the Alzheimer's Clinical Trials Consortium (ACTC)

The [ACTC](#), funded by the National Institute on Aging at the National Institutes of Health (grant number U24AG057437), provides the infrastructure for academic clinical trials in Alzheimer's disease and related dementias. The consortium, jointly based at the University of Southern California, Harvard University and the Mayo Clinic, includes expert units to support clinical trial design, biostatistics, informatics, medical safety, regulatory oversight, recruitment, clinical operations, data management, site monitoring, a biomarker laboratory and repository and neuroimaging. The ACTC includes 35 primary clinical sites across the United States.

About Cognition Therapeutics

Cognition Therapeutics, Inc. has discovered and is developing a pipeline of novel, disease modifying, oral drug candidates to treat a broad array of neurodegenerative disorders. Our molecules uniquely block the toxic action of protein oligomers in the CNS. Our lead asset, CT1812, targets the sigma-2 receptor and is in multiple Phase 2 trials for Alzheimer's disease. Our Phase 2 study in collaboration with ACTC is supported by a competitive grant from the National Institute on Aging. Additional information about Cognition and its product candidates may be found online at www.cogrx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" concerning the development and commercialization of Cognition's products, the potential benefits and attributes of such products, and Cognition's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Cognition undertakes no obligation to update any forward-looking statements for any reason.

CT1812 is an investigational product and neither its use nor the tradename has been approved by the FDA.