



Cognition Therapeutics Completes Enrollment in Phase 2 SHINE Study of CT1812 in Mild-to-Moderate Alzheimer's Disease

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- Top-line results expected mid 2024 -
- Strong physician interest drove SHINE study completion -

PURCHASE, N.Y., Nov. 07, 2023 (GLOBE NEWSWIRE) -- [Cognition Therapeutics, Inc. \(Nasdaq: CGTX\)](#), (the "Company" or "Cognition"), today announced that the last participant was randomized in the Phase 2 SHINE study ([NCT03507790](#)) of CT1812, the company's lead candidate for the treatment of age-related neurodegenerative diseases of the CNS and retina. A total of 153 adults with mild-to-moderate (MMSE 18-26) Alzheimer's disease were randomized to receive either placebo or oral doses of CT1812 (100 mg or 300 mg). Endpoints include safety, change in cognitive function, as measured by ADAS-Cog 11 and biomarker evidence of disease modification. Top-line results are expected in mid 2024 after the last participants have completed six months of treatment.

"Results of the SHINE trial will provide important information on safety, tolerability and cognitive effects of CT1812 in people with mild-to-moderate Alzheimer's disease, and these results will inform our plans for Phase 3 development," [Lisa Ricciardi](#), president and CEO of Cognition Therapeutics stated. "Completing enrollment in the trial ahead of our 2023 target allows us to bring proof-of-concept results sooner and provides savings to our company. We couldn't have accomplished this without the support of the study participants and caregivers as well as our investigators and collaborators at the National Institute on Aging. We look forward to seeing the full study results in mid 2024."

An evaluation of the first 24 SHINE participants showed that those treated with CT1812 experienced a slowing of cognitive decline as measured by a three-point difference on the ADAS-Cog 11 scale compared to placebo. Overall, CT1812 was well tolerated and adverse events were balanced across treatment groups, consistent with the safety profile observed in previous clinical trials.

"Results from our initial clinical trials with CT1812 have shown evidence of target engagement, a positive effect on neurophysiological, anatomical and cognitive endpoints, and biomarker evidence of an impact on underlying disease processes," added [Anthony Caggiano, MD, Ph.D.](#), CMO and head of R&D at Cognition Therapeutics. "We are optimistic about these combined findings and are looking forward to analyzing the final SHINE results."

The SHINE study was supported by two grant awards from the National Institute on Aging of the National Institutes of Health (NIH) totaling approximately \$30 million.

About the SHINE Study

The SHINE study is a double-blind, placebo-controlled Phase 2 clinical trial designed to enroll approximately 144 patients with mild-to-moderate Alzheimer's disease. Participants are evenly randomized to receive either placebo or one of two doses of CT1812 (100 mg or 300 mg), which is taken orally daily for six months. Endpoints include safety, cognitive function as measured by the ADAS-Cog 11, a globally recognized cognitive scale, and biomarker evidence of disease modification.

About CT1812

CT1812 is an experimental orally delivered small molecule that penetrates the blood-brain barrier and binds selectively to the sigma-2 (σ -2) receptor complex. Preclinical and clinical data demonstrate that this binding results in the displacement of toxic A β oligomers. The σ -2 receptor complex is involved in the regulation of key cellular processes such as membrane trafficking and autophagy that are damaged by toxic interaction with A β oligomers, oxidative stress and other stressors. This damage to sensitive synapses can progress to a loss of synaptic function, which manifests as cognitive impairment and Alzheimer's disease progression.

Participants are currently being recruited in the SHIMMER study ([NCT05225415](#)) of CT1812 in adults with dementia with Lewy bodies; the START study ([NCT05531656](#)) of CT1812 in adults with early Alzheimer's disease; and the MAGNIFY study ([NCT05893537](#)) in adults with geographic atrophy (GA) secondary to dry age-related macular degeneration.

About Cognition Therapeutics, Inc.

Cognition Therapeutics, Inc. is a clinical-stage biopharmaceutical company engaged in the discovery and development of innovative, small molecule therapeutics targeting age-related degenerative disorders of the central nervous system and retina. We are currently investigating our lead candidate CT1812 in [clinical programs](#) in Alzheimer's disease, dementia with Lewy bodies (DLB) and dry age-related macular degeneration (dry AMD). We believe CT1812 and our pipeline of σ -2 receptor modulators can regulate pathways that are impaired in these diseases. We believe that targeting the σ -2 receptor with CT1812 represents a mechanism functionally distinct from other current approaches in clinical development for the treatment of degenerative diseases. More about Cognition Therapeutics and its [pipeline](#) can be found at <https://cogrx.com>

Forward Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding our product candidates, including CT1812, and any expected or implied benefits or results, including that initial clinical results observed with respect to CT1812 will be replicated in later trials and our clinical development plans, are forward-looking statements. These statements, including statements relating to the timing and expected results of our clinical trials involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results,

performance, or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “should,” “expect,” “plan,” “aim,” “seek,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “forecast,” “potential” or “continue” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: competition; our ability to secure new (and retain existing) grant funding; our ability to grow and manage growth, maintain relationships with suppliers and retain our management and key employees; our ability to successfully advance our current and future product candidates through development activities, preclinical studies and clinical trials and costs related thereto; uncertainties inherent in the results of preliminary data, pre-clinical studies and earlier-stage clinical trials being predictive of the results of early or later-stage clinical trials; the timing, scope and likelihood of regulatory filings and approvals, including regulatory approval of our product candidates; changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business or competitive factors, including ongoing economic uncertainty; our estimates of expenses and profitability; the evolution of the markets in which we compete; our ability to implement our strategic initiatives and continue to innovate our existing products; our ability to defend our intellectual property; the impact of the COVID-19 pandemic on our business, supply chain and labor force; and the risks and uncertainties described more fully in the “Risk Factors” section of our annual and quarterly reports filed with the Securities Exchange Commission and are available at www.sec.gov. These risks are not exhaustive, and we face both known and unknown risks. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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