



Cognition Therapeutics Completes Enrollment in Phase 2 SHIMMER Study of CT1812 in Mild-to-Moderate Dementia with Lewy Bodies

Apr 29, 2024 |

- Top-line Results Expected in the Second Half of 2024 -

PURCHASE, N.Y., April 29, 2024 (GLOBE NEWSWIRE) -- [Cognition Therapeutics, Inc.](#) (the "Company" or "Cognition") (NASDAQ: CGTX), a clinical stage company developing drugs that treat neurodegenerative disorders, today announced that the company has reached target enrollment in the randomized, placebo-controlled Phase 2 SHIMMER (COG1201) study ([NCT05225415](#)), which is examining the safety and effectiveness of CT1812 in adults with mild-to-moderate dementia with Lewy bodies (DLB). Top-line results are expected in the second half of 2024 after the last participants have completed six months of treatment.

"There are currently no approved disease-modifying therapies for DLB, leaving people living with this disease in desperate need of treatment options," [Lisa Ricciardi](#), president and CEO of Cognition Therapeutics, stated, "The majority of patients with DLB have both A β and α -synuclein pathology. Because of our unique mechanism of action that targets both A β and α -synuclein oligomers, we believe that CT1812 may be able to slow the progression of disease."

The SHIMMER study will assess safety and changes in cognition and executive function as measured by validated scales including the Montreal Cognitive Assessment (MoCA) and Cognitive Drug Research Battery (CDR) tools. In addition, biomarker evidence of disease modification and target engagement will be analyzed. Once available, the company anticipates reporting topline results in a press release and later presenting them at an appropriate medical meeting.

Ms. Ricciardi concluded, "I want to thank the patients, investigators and clinical partners who participated in SHIMMER. We look forward to analyzing the final results and reporting them later this year."

About the SHIMMER Study

The SHIMMER study is a double-blind, placebo-controlled Phase 2 clinical trial designed to enroll 120 adults with mild-to-moderate DLB. Participants are evenly randomized to receive either placebo or one of two oral once-daily doses of CT1812 (100 mg or 300 mg) for six months. The SHIMMER study is supported by a grant award from the National Institute on Aging of the National Institutes of Health (NIH) totaling approximately \$30 million and is being conducted in collaboration with James E. Galvin, MD, MPH, director of the Comprehensive Center for Brain Health at the University of Miami Miller School of Medicine and the Lewy Body Dementia Association (LBDA). The SHIMMER study is being conducted at over 30 sites in the United States, many of which are LBDA centers of excellence.

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, which is involved in the regulation of key cellular processes such as membrane trafficking and autophagy. These processes are disrupted by toxic interaction with oligomers of A β or α -synuclein, oxidative stress and other drivers of neurodegenerative disease. The ensuing damage to sensitive synapses can progress to a loss of synaptic function, which manifests as cognitive impairment, loss of motor or executive function and progression of disease.

CT1812 is currently being studied in several clinical trials, including the aforementioned SHIMMER study; two Phase 2 studies in Alzheimer's disease including the START study ([NCT05531656](#)) in adults with MCI or early Alzheimer's disease and the SHINE study ([NCT03507790](#)), which has concluded enrollment in adults with mild-to-moderate disease; and the MAGNIFY study ([NCT05893537](#)) in adults with geographic atrophy (GA) secondary to dry age-related macular degeneration.

The company expects to report topline results from the Phase 2 SHINE clinical trial in mid-2024. A virtual KOL event was conducted recently with experts who discussed, the currently approved immunotherapies for early Alzheimer's disease, their commercial uptake, and the potential for other therapeutic modalities to improve upon their clinical effectiveness through combination or sequential therapy. The archive of this event may be viewed here: <https://lifescievents.com/event/cognition/>.

About Dementia with Lewy Bodies

An estimated 1.4 million Americans are living with DLB, a progressive disease that accounts for approximately 5-10% of all dementia cases. Approximately 50% of people with DLB have A β co-pathology as well as symptomology of Parkinson's and Alzheimer's diseases, making it challenging to diagnose. DLB is caused by a build-up of a protein, α -synuclein, which forms deposits, called Lewy bodies, in the brain. Oligomers of α -synuclein are highly toxic and bind to neurons where they impair critical cellular processes, causing synaptic dysfunction and loss. Patients with DLB often experience cognitive, physical, sleep and behavioral symptoms, including hallucinations, delusions and mood changes. There are currently no disease-modifying treatments approved for DLB patients.

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](https://cogrx.com) 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, the timing and expected results of our clinical trials 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 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; impacts of ongoing global and regional conflicts; 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.

Contact Information:
Cognition Therapeutics, Inc.
info@cogrx.com

Casey McDonald (media)
Tiberend Strategic Advisors, Inc.
cmcdonald@tiberend.com

Mike Moyer (investors)
LifeSci Advisors
mmoyer@lifesciadvisors.com