



First Participant Dosed in Europe as Cognition Therapeutics Expand Phase 2 Alzheimer's Disease Clinical Trial of Oral CT1812

December 15, 2022

SHINE Study Expanded from USA to Include sites in Spain, the Netherlands, and Czech Republic

PURCHASE, N.Y., Dec. 15, 2022 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc. (Nasdaq: CGTX) (the "Company" or "Cognition"), announced that the Phase 2 SHINE clinical trial of CT1812, an experimental oral, once-daily capsule in development for mild-to-moderate Alzheimer's disease, has been expanded into clinical sites in Spain, the Netherlands, and the Czech Republic. CT1812 is designed to modulate a key cellular receptor known as sigma-2 and block oligomers from binding to neurons, thus preventing their synaptotoxic effects. This new mechanism of action is fundamentally distinct from and complementary with that of anti-amyloid antibody-based immunotherapy, such as lecanemab.

Brain Research Center in Amsterdam, The Netherlands is the first European site to enroll participants in the Phase 2 SHINE study being conducted in approximately 144 individuals. Dr. Niels Prins, director of the Center stated, "We are committed to offering Alzheimer's patients and their families access to innovative clinical trials, such as the SHINE study of CT1812. With our industry partners, we believe we can make inroads in development of new medicines to slow the progression of Alzheimer's and related disorders."

[Anthony O. Caggiano, M.D., Ph.D.](#), Cognition's chief medical officer and head of R&D added, "We believe that the approach of targeting soluble oligomeric A β species has been validated by lecanemab findings announced earlier this year by Eisai and Biogen at CTAD 2022. However, unlike antibodies, which lower brain amyloid levels, CT1812 was designed to shield neurons from these toxic proteins."

Results from initial trials with CT1812 provided evidence to support expansion of the clinical programs. In particular, positive trends were seen in cognition, MRI volumetric imaging and proteomic biomarkers:

- Slower decline in ADAS-cog vs placebo over six months
- Preservation of brain volume (composite) vs placebo with statistically significant ($p < 0.05$) improvement in volume in three regions of interest
- Normalization of biomarkers associated with Alzheimer's pathology

The SHINE study is supported by approximately \$30 million in grant funding from the National Institutes on Aging (NIA).

"We are grateful for the continued support of the NIA to accelerate the clinical development of CT1812 and advance our understanding of σ -2 biology in both Alzheimer's disease and dementia with Lewy bodies," added Cognition president and CEO, [Lisa Ricciardi](#). "We appreciate the sense of urgency shown by Dr. Prins and his colleagues at Brain Research Center Amsterdam, who worked diligently to expedite their site activation and enroll Europe's first patient in the SHINE trial."

About the SHINE Study

The SHINE study is a double-blind, placebo-controlled Phase 2 clinical trial designed to enroll up to 144 participants with mild-to-moderate Alzheimer's disease. In addition to background therapies, participants will be randomized to receive either placebo or one of two doses of CT1812, taken orally daily for six months. Endpoints include safety and biomarker evidence of disease modification as well as cognitive function, as measured by the ADAS-Cog 11, a globally recognized cognitive scale. More information about the SHINE study may be found at www.shineADstudy.com. In the Netherlands, please visit [Brain Research Center](#).

About CT1812

CT1812 is an oral small molecule designed to penetrate the blood-brain barrier and bind selectively to the sigma-2 (σ -2) receptor complex. 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.

CT1812 is an experimental candidate and has not been approved by the U.S. FDA or other regulatory agency. It is currently in development for mild-to-moderate Alzheimer's disease in the SHINE study ([NCT03507790](#)) and dementia with Lewy bodies in the SHIMMER study ([NCT05225415](#)).

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 cash and financial resources 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) non-dilutive 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; 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; 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 in the “Risk Factors” sections of our filings with the Securities Exchange Commission. 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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