



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

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Innovative Trial Explores Theta Wave qEEG as a Biomarker of Synaptic Dysfunction

NEW YORK, Feb. 09, 2023 (GLOBE NEWSWIRE) -- [Cognition Therapeutics, Inc.](#) (Nasdaq: CGTX), a clinical stage neuroscience company developing drugs that treat neurodegenerative disorders by regulating cellular damage response pathways, today announced that enrollment has completed in the randomized, double-blind Phase 2 SEQUEL study (COG0202, [NCT04735536](#)) of CT1812 in 16 adults with mild-to-moderate Alzheimer's disease. The study was designed to assess differences in synaptic function in CT1812- versus placebo-treated participants using quantitative electroencephalogram (qEEG) to measure theta waves, the type of brain activity most commonly associated with processing information and memory formation. Topline results from SEQUEL are expected mid-2023.

There is substantial evidence that A β oligomers have the potential to impair synaptic and neuronal activity. The use of qEEG allows this decline in synaptic activity to be observed as a change in neural oscillation –the natural ebb and flow of electrical activity that is associated with normal communication between neurons. As a fast and cost-effective method of measuring the electrical activity of the brain, qEEG may represent a non-invasive biomarker of Alzheimer's disease progression and treatment effect.

"We have previously shown that qEEG can detect changes in whole-brain electrical patterns as well as regional patterns associated with the coordinated transfer of information that is required for executive function in Alzheimer's disease," explained Everard (Jort) Vijverberg, M.D., Ph.D., a neurologist and senior researcher at the Amsterdam University Medical Centers and principal investigator in SEQUEL. "In the SEQUEL study, we use qEEG as an experimental outcome measure to determine the effect of CT1812 on Alzheimer disease processes in the brain. We expect results will show that untreated Alzheimer's patients experience an increase in theta power and a decrease of the alpha band, which may indicate a slowing of brain activity."

CT1812 is an oral small molecule designed to bind selectively to the sigma-2 (σ -2) receptor and displace beta amyloid (A β) oligomers from synapses. Soluble A β oligomers and protofibrils have been recognized as the most neurotoxic form of amyloid in the literature and recently through validating research published by Eisai in the *New England Journal of Medicine*.

"If we demonstrate that CT1812 treatment can normalize qEEG patterns in SEQUEL by decreasing theta power relative to placebo, it may provide evidence that we are protecting synapses from the toxicity of A β oligomers," added [Anthony Caggiano, M.D., Ph.D.](#), Cognition's chief medical officer and head of R&D.

About the SEQUEL Study

The SEQUEL study enrolled 16 adults with mild-to-moderate Alzheimer's disease (MMSE 18-26), each of whom were randomized to receive either CT1812 or placebo once daily for 28 days. After a 14-day wash-out period, participants cross over into the other treatment arm for an additional 28 days. SEQUEL was designed to assess the safety and efficacy of CT1812 and to measure the impact of CT1812 on the electrical activity in the brain, specifically those electrical impulses in the theta band.

SEQUEL is supported by \$5.3 million in grant awards (R01AG058710) by the National Institute of Aging (NIA) of the National Institutes of Health (NIH).

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 www.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 benefits or results, our clinical development plans,

including the expected timing of topline results from SEQUEL, 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 and pre-clinical studies being predictive of the results of 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 ongoing COVID-19 pandemic on our business, supply chain and labor force; and the risks and uncertainties described in the “Risk Factors” section of our annual and quarterly reports filed the Securities Exchange Commission. 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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