Cognition Therapeutics Announces Positive Topline Results for CT1812 Phase 2 SEQUEL Study for Mild-to-Moderate Alzheimer's Disease

June 28, 2023

Results Show Positive Treatment Effect of CT1812 on Global and Regional Brain Activity

Management Holding Webcast Conference Call at 8:00am ET Today

NEW YORK, June 28, 2023 (GLOBE NEWSWIRE) -- **Cognition Therapeutics, Inc.** (NASDAQ: CGTX), a clinical-stage neuroscience company developing drugs that treat age-related degenerative disorders by regulating cellular damage response pathways, today announced topline results from its Phase 2 double-blind, single-crossover SEQUEL study (NCT04735536) of CT1812 in 16 adults with mild-to-moderate Alzheimer's disease. The study, which was conducted in the Netherlands, met its primary endpoints for safety and tolerability and showed positive effects for CT1812-treated participants as measured via quantitative electroencephalogram (qEEG).

Research suggests that overall slowing of brain activity in Alzheimer's disease can be measured by an increase in relative theta power using qEEG and other measures of brain connectivity. The SEQUEL study examined brain wave changes over 4 weeks of treatment and showed that participants treated with CT1812 experienced a numerical reduction in relative theta power compared to the period when they were on placebo. While not statistically significant, these data indicate a positive impact on underlying brain function and are supported by nominally significant and directionally positive changes in AECc and alpha power.

In addition to global measures of brain activity, this study assessed brainwave changes in frontal, central, temporal and posterior (occipital and parietal) regions. Treatment with CT1812 was associated with decreases in relative theta in each of these regions, with statistical significance in the change in relative theta in the central region.

"My colleagues and I are excited to see this favorable result, which suggests that treatment with CT1812 may be directly impacting overall brain health, as illustrated in a change in relative theta power globally and across brain regions," said Everard (Jort) Vijverberg, M.D., Ph.D., a neurologist and senior researcher at the Amsterdam University Medical Centers, and principal investigator in SEQUEL. "We look forward to continuing our work with Cognition as a clinical trial collaborator in the SHINE study, which is studying CT1812 over a six-month treatment period in 144 adults with mild-to-moderate Alzheimer's disease."

In addition to changes in theta wave patterns, an AECc analysis of the qEEG results showed that CT1812 treatment was associated with nominally statistically significantly greater connectivity between brain regions. The brain's ability to communicate and exchange information between regions is critical to cognition.

"While the study of brain connectivity is evolving, many consider this to be a highly relevant measure, as it demonstrates how well a brain network is functioning," added explained Willem de Haan, M.D. Ph.D., a neurologist and senior researcher at the Amsterdam University Medical Centers' Alzheimer Center. "The positive insights derived from this study could encourage other researchers and industry members to use qEEG as a measurement tool during clinical trials, as well as healthcare professionals monitoring disease progression and during the delivery of care."

As observed in previous studies, CT1812 was well-tolerated in the SEQUEL study with most adverse events being mild-to-moderate in severity. There were no treatment-related SAEs reported.

The SEQUEL study, which was supported by a grant from the National Institute on Aging (R01AG058710), was designed to assess differences in synaptic function in CT1812-treated versus placebo-treated participants using qEEG to measure changes in brain wave patterns. The sophisticated algorithms used by qEEG allow small changes in brain activity to be quantified. The changes in amplitude and frequency of wavebands over time can provide insight into the levels of activity in and between brain regions. 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.

"Though an exploratory endpoint, there is substantial evidence to believe that qEEG can detect changes in both whole-brain and regional electrical patterns that are impaired in Alzheimer's disease," said Anthony Caggiano, M.D., Ph.D., Cognition's chief medical officer and head of R&D. "These results show CT1812's impact on neurophysiological endpoints, which add to the growing body of evidence that we have compiled in our preclinical and clinical programs: CT1812's target engagement observed in the SNAP study, its impact on anatomical endpoints observed in the SPARC study, and preliminary cognitive impact seen in the first cohort of patients in the SHINE study."

Lisa Ricciardi, CEO of Cognition Therapeutics, added, "Each of our specialty pharmacology studies and our extensive biomarker analyses have supported the findings from our preclinical studies and provided us with important insights into the role of the σ-2 receptor and the potential impact of treatment with CT1812. We are increasingly optimistic about the larger patient studies that are underway in Alzheimer's disease, as well as in dementia with Lewy bodies and dry age-related macular degeneration where we think the protective cellular role may further benefit patients."

Ms. Ricciardi concluded, "We feel fortunate to announce positive findings from SEQUEL during this period when the community is commemorating Alzheimer's & Brain Awareness Month. During June in particular we recognize the challenges of Alzheimer's and other dementias that affect more than 55 million people worldwide. It gives us the opportunity to reflect and recommit to our mission to bring effective treatment to those suffering from these devastating diseases."

Full analyses of the results from SEQUEL will be presented at an upcoming medical meeting, as will analyses of Alzheimer's canonical biomarkers and proteomics from fluid samples collected from SEQUEL participants.

Webcast and Conference Call
Cognition will host a conference call and webcast on June 28, 2023, at 8:00am ET to discuss these topline results. The call can be accessed by dialing (800) 715-9871 for U.S. Callers and (646) 307-1963 for international callers five minutes prior to the start of the call and providing the conference ID 7557195. A live webcast will be available on the company's website at www.cogrx.com/events and will be archived for 90 days.

About CT1812
CT1812 is an experimental orally delivered 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 soluble beta amyloid (Aβ) 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 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 investigational 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 http://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 the 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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