Cognition Therapeutics and Collaborators at Yale and ACTC Announce Oral Late-breaking Presentation on the START Study in Early Alzheimer's Disease at CTAD

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NEW YORK, Oct. 27, 2023 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc. (NASDAQ: CGTX) announced that Christoper van Dyck, M.D., the director of the Yale Alzheimer's Disease Research Unit and the Yale Alzheimer's Disease Research Center, is presenting the Phase 2 study design of the company's ongoing START study in an oral late-breaking session at Clinical Trials on Alzheimer's Disease (CTAD) conference. The START Study is assessing once-daily oral CT1812 or placebo in 540 individuals with early Alzheimer's disease for 18 months of treatment. Cognition Therapeutics is conducting the study in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC) with major grant support from the National Institute of Aging (NIA) at the National Institutes of Health.

"This study represents the next generation of trials for Alzheimer's disease, in that participants who are on stable doses of the first fully approved disease-modifying treatment for Alzheimer's disease - lecanemab (an anti-amyloid antibody) - will be eligible to enroll, in addition to those who have not been exposed to lecanemab," explained Dr. van Dyck, who is also a member of the ACTC executive committee and the project director of the START Study. "The future treatment of Alzheimer's disease will likely consist of combination therapies to achieve greater slowing of disease progression. My colleagues and I are excited about the prospects of an oral treatment like CT1812, which may prove to be effective as a monotherapy but also has a mechanism of action that is distinct from and potentially complimentary to the anti-amyloid antibodies."

Published data points to a role for the sigma-2 (σ-2) receptor in regulating key "housekeeping" processes such as autophagy that are impaired in Alzheimer's and other neurodegenerative diseases. By binding to the σ-2 receptor on neurons, CT1812 may rescue these processes and protect neurons from further damage. We have collected the following clinical data, which we believe support the potential benefit that CT1812 may exert on synapse function and overall brain health:

- target engagement data demonstrated in the SNAP study;
- preliminary evidence of cognitive impact seen in the first cohort of patients in the SHINE study;
- reduced hippocampal atrophy (loss of brain matter) observed via volumetric MRI in the SPARC study; and
- favorable impact on brainwave patterns as measured via quantitative electroencephalogram in the Phase 2 SEQUEL study.

The tolerability profile of CT1812 has been consistent throughout clinical development with mild-to-moderate adverse events and no treatment-related serious adverse events reported.

The START study is actively underway with screening of adults with early Alzheimer's disease at multiple clinical sites, including the University of Kentucky Sanders-Brown Center on Aging (SBCoA), the Butler Hospital Memory and Aging Program (BHMAP), and Wake Forest University Health Sciences. Ultimately, we expect that approximately 50 sites in North America, including premier institutions in the ACTC network, will be activated.

"A once-daily oral medication that could slow or halt the progression of this disease at an early stage would add an important therapeutic option for physicians and patients alike," added Cognition president and CEO, Lisa Ricciardi. "This trial gives us the opportunity to study CT1812 in patients with early stages of Alzheimer's disease, when the proposed synapto-protective mechanism of CT1812 may shield neurons from further injury. We believe that a trial that reflects the future real-world population of individuals who are on or have been exposed to anti-amyloid antibodies, will allow for clinically relevant findings from the study."

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 Aβ oligomers, oxidative stress and other stressors. This damage to sensitive synapses can progress to a loss of synaptic function. CT1812 is currently in development for mild-to-moderate Alzheimer's disease in the SHINE study (NCT03507790), early Alzheimer's disease in the START study (NCT05531656), and dementia with Lewy bodies in the SHIMMER study (NCT05225415).

About the START Study
The START study will measure the efficacy and tolerability of once-daily oral CT1812 in individuals with mild cognitive impairment or early Alzheimer's disease (MMSE 20-30) who have elevated Aβ (as measured by PET or CSF). Participants will be randomized to receive CT1812 or placebo for 18 months. The study will assess cognition and executive function using validated tools including the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB) and ADAS-Cog rating scales, as well as biomarker and safety findings.

The START study is supported by a grant from the National Institute of Aging (NIA) at the National Institutes of Health (R01AG065248). The study is being conducted in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC), an NIA-funded (grant number U24AG057437) clinical trial network of 35 leading academic sites with expertise in clinical trials in Alzheimer's disease. More information may be found at https://start-study.org.

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 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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