Cognition Therapeutics and the Alzheimer's Clinical Trials Consortium Initiate First Clinical Site in the Phase 2 START Study in Early Alzheimer’s Disease

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NEW YORK, July 05, 2023 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc. (NASDAQ: CGTX) announced that the first clinical trial site has been activated and can begin recruiting participants for the 540-patient Phase 2 START study of CT1812 in adults with early Alzheimer’s disease. The University of Kentucky Sanders-Brown Center on Aging (SBCoA) is the first of approximately 50 sites in North America that has been activated by the Alzheimer's Clinical Trials Consortium (ACTC). The ACTC, founded in 2018 with funding from the National Institute on Aging (NIA), part of the National Institutes of Health, is one of the NIA's largest public-private partnerships.

“Our START study represents a unique and important opportunity for Cognition to study CT1812 in people with early Alzheimer's disease,” added Cognition president and CEO, Lisa Ricciardi. While trials in this patient population are crucial, the long treatment period required to show a change in cognition can be overly burdensome for small biotechnology companies. Without the support of the ACTC and the NIA's $81 million grant, we would likely not be in a position to offer these research participants the opportunity to test an oral once-daily medication that may slow the progression of Alzheimer's disease. It is incredibly exciting and humbling to have reached the stage where patient recruitment can finally begin.”

The randomized placebo-controlled START trial is being conducted at approximately 50 sites in North America including over 30 premier academic institutions that are part of the ACTC network. An estimated 540 adults with early Alzheimer’s disease (MMSE 20-30) who have elevated beta amyloid (Aβ) will be randomized to receive once-daily oral CT1812 or placebo for 18 months. CT1812 is an investigational oral, small molecule designed to bind to a receptor on synapses and prevent the toxic effects of soluble Aβ oligomers on neurons.

“The hard work from our dedicated team of clinical program managers, statisticians, biomarker experts, and recruitment, retention and diversity leaders has paid off with the activation of the site at the SBCoA,” concluded Paul Aisen, M.D., professor of neurology at the University of Southern California and director of the Alzheimer's Therapeutic Research Institute. “We’re looking forward to partnering with the team at SBCoA and other investigators who are working to bring their sites online so we can begin screening people with early Alzheimer’s disease who are interested in becoming participants in the START study.”

To date, CT1812 has been studied in over 200 healthy volunteers and adults with Alzheimer's disease or dementia with Lewy bodies (DLB). The tolerability profile of CT1812 has been consistent throughout clinical development. Most adverse events have been mild to moderate in severity with no deaths and no treatment-related serious adverse events reported. We have observed mild and transient elevations of liver enzymes without any other indications of liver injury, which returned to normal after cessation of treatment.

More information about the START study may be found on www.clinicaltrials.gov under trial identifier NCT05531656.

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, 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 the Alzheimer's Clinical Trials Consortium (ACTC)
The ACTC, funded by the National Institute on Aging at the National Institutes of Health (grant number U24AG057437), provides the infrastructure for academic clinical trials in Alzheimer's disease and related dementias. The consortium, jointly based at the University of Southern California, Harvard University and the Mayo Clinic, includes expert units to support clinical trial design, biostatistics, informatics, medical safety, regulatory oversight, recruitment, clinical operations, data management, site monitoring, a biomarker laboratory and repository and neuroimaging. The ACTC includes 35 primary clinical sites across the United States.

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, 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, including statements regarding our Phase 2 START study of CT1812, 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 more fully described 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

Daniel Kontoh-Boateng (investors)
Tiberend Strategic Advisors, Inc.
dboateng@tiberend.com