Cognition Therapeutics Presents New Data at CTAD Conference from Advancing Pipeline Across Multiple CNS Indications

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Complete EEG results from SEQUEL study to be unveiled, demonstrating beneficial impact of CT1812 on brain synaptic function

CT1812 START study in early Alzheimer's disease allows approved monoclonal antibody as background therapy – featured as late-breaking, oral presentation

PURCHASE, N.Y., Oct. 16, 2023 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc., (Nasdaq: CGTX), (the "Company" or "Cognition") announced upcoming presentations from studies of CT1812, the Company's lead candidate for the treatment of adults with early, mild and moderate Alzheimer's disease at the Clinical Trials on Alzheimer's Disease (CTAD) conference being held October 24-27, 2023 virtually and in person in Boston, MA.

Cognition scientists and collaborators will present the complete electroencephalography (EEG) findings and proteomic analyses from the SEQUEL study. Prior topline results showed that CT1812 had a beneficial impact on synapse function as measured by a positive change in brain waves patterns observed using quantitative EEG. Specifically, participants treated with CT1812 exhibited fewer slow "theta" waves, which are associated with cognitive impairment, and proportionally more "alpha" waves compared to placebo-treated participants. CT1812 also improved connectivity, as assessed by alpha AECc, which may indicate improved communication between different parts of the brain.

An oral late-breaking presentation will also discuss the Phase 2 study design of the company's ongoing START study, which is enrolling adults with early Alzheimer's disease. Participants in START will be permitted to be on stable background therapy with lecanemab, an FDA-approved anti-amyloid antibody.

"The approval of monoclonal antibody therapies against amyloid beta (Aβ) protofibrils represents an important milestone in Alzheimer's drug development, but industry experts agree that combination treatments will likely be required to achieve greater impact on the disease," explained Anthony Caggiano, MD, Ph.D., Cognition's CMO and head of R&D. "To this end, we and our colleagues at the National Institute of Aging and the Alzheimer's Clinical Trials Consortium (ACTC) made the strategic decision to allow participants to enroll in the ongoing Phase 2 START study who are being administered lecanemab. We believe this will allow us to assess the benefit of CT1812 in real-world conditions."

Cognition Therapeutics at CTAD:

Title:	A Pilot Electroencephalography (EEG) Study to Evaluate the Effect of CT1812 Treatment on Synaptic Activity in Subjects with Mild to Moderate Alzheimer's Disease (LP024)
Authors:	De Haan W, Caggiano AO, Scheltens P, Grundman M, Scheijbeler E, Hamby ME, Vijverberg E
Title:	Proteomic Analysis of Plasma in a Phase 2 Clinical Trial in Alzheimer's Patients to Identify Pharmacodynamic Biomarkers of the S2R Modulator CT1812 (P075)
Authors:	Lizama B, Cho E, Duong D, Pandey K, Williams C, Caggiano AO, Seyfried N, Di Caro V, Hamby ME
Title:	Proteomic Analysis in a Phase 2 Clinical Trial Studying CT1812 to Identify CSF and Plasma Pharmacodynamic Biomarkers and Molecular Correlates of EEG in Alzheimer's Patients (LP057)
Authors:	Di Caro V, Pandey K, Lizama B, Cho E, Duong D, De Haan W, Grundman M, Seyfried N, Caggiano AO, Vijverberg E, Hamby ME
Title:	CT1812 START Study Design: Anti-Aβ Monoclonal Antibodies as Background Therapy (LB18)
Authors:	van Dyck CH, Raman R, Donohue MC, Rissman RA, Rafii MS, Hamby ME, Grundman M, Caggiano AO, Aisen PS
Session:	Friday, October 27

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 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 was supported by $5.3 million in grant awards by the National Institute of Aging

(R01AG058710). More information may be found on https://clinicaltrials.gov.

About the START Study
The 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.

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