Cognition Therapeutics CEO Issues Letter to Shareholders

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Topline data from Phase 2 SHINE trial in patients with mild-to-moderate Alzheimer's disease anticipated in mid 2024

Topline data from Phase 2 SHIMMER trial in mild-to-moderate dementia with Lewy bodies anticipated in the second half of 2024

PURCHASE, N.Y., Jan. 04, 2024 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc. (Nasdaq: CGTX), a clinical-stage neuroscience company developing drugs that treat neurodegenerative disorders by regulating cellular damage response pathways (the “Company” or “Cognition”), today announced that CEO Lisa Ricciardi has issued a Letter to Shareholders to provide an update on recent pipeline developments and a preview of the company’s strategy in 2024. The full text of the letter follows:

A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER

To my fellow shareholders,
The year ahead holds great promise for Cognition Therapeutics. We are anticipating proof-of-concept data from two Phase 2 neurodegenerative disease studies of our lead clinical oral product candidate, CT1812: the SHINE trial in mild-to-moderate Alzheimer's disease and the SHIMMER trial in mild-to-moderate dementia with Lewy bodies (DLB). As we work towards these important milestones, we take stock of the achievements that give rise to optimism at Cognition Therapeutics and in the broader medical community.

With the landmark approval of the first disease-modifying anti-amyloid drugs, patients and their families can access treatments to slow the progression of Alzheimer's disease. These anti-beta amyloid (Aβ) antibodies generated excitement in the field even before their approval, confirming for researchers that targeting toxic Aβ oligomers and protofibrils – the most toxic forms of the protein – could have meaningful clinical results. For many researchers these findings validated decades of work and gave us hope that the successes of 2023 will lead to further progress in the development of new candidates; to improve on and/or complement these new antibody therapies. We believe that CT1812’s unique mechanism of protecting synapses from Aβ oligomers by blocking them from binding to neurons could provide therapeutic benefit alone or in combination with other drugs.

Advances are continuing not only in disease treatment but in the development of tools for diagnosis and monitoring. Results from our studies with fluid biomarkers and instruments like quantitative EEG, as well as those of other innovating companies using these tools, are providing insights into noninvasive ways to diagnose, stage and monitor treatments. The Cognition team continues to advance the field, as witnessed by presentations of proteomics analyses in models of Alzheimer’s and Parkinson’s diseases at the Society for Neuroscience’s Neuroscience 2023 meeting, the presentation of full data from the SEQUEL trial at CTAD 2023 and our manuscript of the complete SPARC results which has been accepted for publication in the journal, *Alzheimer’s Research & Therapy* . Together, results from these studies provide evidence that CT1812 is having an impact on the biology of a range of age-related degenerative diseases and disorders through modulation of the sigma-2 receptor, which itself was the subject of a review article published in March 2023.

With this impressive dossier of preclinical and clinical data for CT1812, we look forward to 2024 as we anticipate achieving key milestones in the coming months.

Key Clinical Milestones Expected in 2024
Our first catalyst in 2024 is expected to occur at mid-year when we unblind topline safety and efficacy data from our Phase 2 SHINE trial of oral CT1812 in adults with mild-to-moderate Alzheimer’s disease. An evaluation of the first 24 SHINE participants showed that those treated with CT1812 experienced a three-point difference in the slowing of cognitive decline compared to placebo, as measured on the ADAS-Cog 11 scale. We are optimistic that the full SHINE data set will corroborate these initial findings and inform our plans for Phase 3 development.

Also in 2024, we anticipate reaching full enrollment for our SHIMMER trial, which is evaluating oral CT1812 in adults diagnosed with mild-to-moderate DLB, the second most common form of dementia. More than half of DLB patients are estimated to have both Aβ and α-synuclein oligomers in the brain. We believe that CT1812, which has been shown to protect neurons from the toxicity of both pathogenic proteins, has the potential to treat this sizable population of DLB patients with co-pathology. We aim to complete enrollment early in 2024 enabling topline data in the second half of the year.

Beyond Mild-to-Moderate Disease, into Early Patients
Our 540-patient START trial in adults with early Alzheimer’s disease is actively recruiting participants from a number of Alzheimer's Clinical Trials Consortium (ACTC) centers of excellence. We and our collaborators on this study made the important decision to allow participants on stable background therapy with lecanemab to enroll in START, which we expect will provide real-world evidence of CT1812’s potential as a monotherapy and in combination with monoclonal antibody treatments.

In addition, our early proteomics analyses and subsequent preclinical work provided compelling evidence that the sigma-2 receptor has an important role in the function of retinal pigment epithelial (RPE) cells, which are necessary for the preservation of vision. This finding led us to expand into a fourth indication and we are actively enrolling participants in our 246-patient MAGNIFY trial for adults with dry age-related macular degeneration (dry AMD) who have measurable geographic atrophy.

Like Alzheimer’s disease, dry AMD also saw its first disease-modifying drug approvals in 2023. The launch of these products represents an important milestone, but we believe that effective, orally available treatment options that employ different modes of action would be well received in the medical and patient communities. For Cognition, expanding the pipeline for CT1812 to dry AMD has the potential to grow Cognition’s value across multiple

age-related diseases. We look forward to a busy year in the vision space, working with retinal specialists to communicate the scientific rationale for using CT1812 in geographic atrophy and supporting enrollment of the Magnify trial.

As we are working towards completion of two studies and advancing two others, I am struck by the incredible dedication of our patients, the families who put their trust in us and our investigators. We could not do this work without our clinical trial partners and our dedicated team.

Sincerely,
Lisa Ricciardi
Chief Executive Officer, Cognition Therapeutics

About Cognition Therapeutics
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, including statements regarding our clinical studies of CT1812 in animal models and any analyses of the results therefrom, 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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