



Cognition Therapeutics Presents Scientific Rationale, Clinical Biomarker and Preclinical Data supporting a Phase 2 Clinical Trial with CT1812 in Geographic Atrophy Secondary to Dry AMD

December 1, 2022

PURCHASE, N.Y., Dec. 01, 2022 (GLOBE NEWSWIRE) -- Cognition Therapeutics, Inc., (Nasdaq: CGTX), (the "Company" or "Cognition") today announced that the scientific rationale, supporting proof-of-concept data and design of the planned Phase 2 trial of CT1812 in [geographic atrophy](#) (GA) secondary to dry age-related macular degeneration (dry AMD) will be communicated in an oral presentation at the 2022 Dry AMD Therapeutic Development Summit. Age-related macular degeneration is the leading cause of irreversible central vision loss in the world, with dry AMD affecting an estimated 10 million people in the U.S., 1.5 million of whom have advanced disease or GA.

"There are currently no approved drugs for dry AMD, and given the severe consequence of disease and enormous patient population, it's imperative that we work towards a treatment," added [Lisa Ricciardi](#), president and CEO of Cognition Therapeutics. "Complement inhibition has shown potential in clinical trials but must be given via intravitreal injection to each affected eye. We believe that a noninvasive oral therapeutic with a novel mechanism of action that can penetrate the blood-retina barrier and treat both eyes simultaneously would be a significant advantage to the millions of people at risk for permanent vision loss."

CT1812 is an experimental oral sigma-2 (σ -2) receptor modulator currently in Phase 2 clinical trials for both [Alzheimer's disease and dementia with Lewy bodies](#) (DLB). An unbiased pathway analysis from two Alzheimer's disease clinical trials identified GA and macular degeneration as two diseases most significantly associated with proteomic changes in CT1812- vs placebo-treated patient biofluids. Further analysis of the proteomes identified key proteins and pathways impaired in dry AMD and GA that were significantly impacted by CT1812 treatment, providing evidence that a σ -2 receptor modulator may have therapeutic potential in dry AMD.

Subsequently, *in vitro* studies were conducted using RPEs derived from induced pluripotent stem cells (iPSC) that were exposed to amyloid beta oligomers and oxidative stress. Results from these studies demonstrated that administration of CT1812 can rescue the ability of RPEs to recycle photoreceptor outer segments (POS), a vital process that is damaged by stressors including oxidative stress and pathogenic proteins.

"The proteomic analyses from our clinical studies in neurodegenerative disease were instrumental in identifying dry AMD as an indication of interest," explained [Mary Hamby, Ph.D.](#), VP of biology at Cognition Therapeutics. "Published genetic and preclinical findings from independent laboratories supported the role of the σ -2 receptor in dry AMD and our data provide evidence that modulation of the σ -2 receptor may protect sensitive RPE cells and rescue functional deficits. Our next step is to test this novel mechanistic approach in the clinic."

Based on several lines of evidence including these clinical proteomic analyses and preclinical data in RPE cell models, Cognition has entered discussions with the U.S. Food and Drug Administration (FDA) to initiate a Phase 2 clinical trial in over 200 people with GA. The full complement of evidence supporting Cognition's advancement of CT1812 into the clinic, along with the design of the proposed Phase 2 study, will be presented at the [Dry AMD Therapeutic Development Summit](#).

Presentation details:

Date/Time: December 1, 2022
Title: Targeting the Sigma-2 Receptor (S2R) for Dry AMD with an Oral Small Molecule Approach: Preclinical & Clinical Biomarker Support
Author: Vice President of Research, Mary Hamby, Ph.D.

About Dry Age-related Macular Degeneration

Dry AMD affects an estimated 10 million people in the U.S., 1.5 million of whom have advanced disease or geographic atrophy. Dry AMD is characterized by a progressive deterioration of the macula, a region of the retina comprised of photoreceptors, specialized neurons that convert light into electrical signals, and a layer of retinal pigment epithelial (RPE) cells, which forms the blood-retinal barrier and provides essential support functions to photoreceptors. Macular deterioration is believed to be caused by several factors, including oxidative stress, inflammation and the buildup of protein deposits called drusen, which form on the Bruch's membrane below the RPE. A key function performed by RPE cells is the recycling of photoreceptor outer segments (POS). This process is impaired in dry AMD, resulting in the eventual loss of photoreceptors, which in turn leads to irreversible vision loss.

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 cash and financial resources and our clinical development plans, are forward-looking statements. These statements 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) non-dilutive 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; 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 we may be adversely affected by other economic, business or competitive factors; 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 in the “Risk Factors” sections of our filings with the Securities Exchange Commission. 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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