Cognition Therapeutics Announces First Patient Dosed in SEQUEL Study of CT1812

August 27, 2020

Pittsburgh, August 27, 2020 —Cognition Therapeutics, Inc., a clinical stage neuroscience company developing drugs that treat neurodegenerative disorders by regulating cellular damage response pathways announced that it has dosed the first patient in the SEQUEL (Study of EEG QUantification with ELayta) Study of CT1812 (Elayta™) in adults with mild-to-moderate Alzheimer's disease. The study is taking place at the Amsterdam University Medical Center (VUmc) with Philip Scheltens, M.D., Ph.D., director of the VuMC Alzheimer Center, serving as primary investigator. Sixteen adults with Alzheimer's disease will be enrolled and randomized to treatment with CT1812 or placebo. Primary outcome of the study is quantitative EEG (qEEG) as a measure of the physiological effects of CT1812.

"SEQUEL will investigate whether the displacement of beta amyloid (Aβ) oligomers – a protein highly toxic to synapses – by CT1812 results in an increase in the brain's electrical activity that is detectable by qEEG," explained Professor Scheltens. "Detecting a difference between Alzheimer's patients treated with CT1812 versus placebo would be an important finding for Cognition, as it would provide further evidence of the drug's protection of synapses. Moreover, this discovery would have enormous impact on the larger field of neurology, as it would provide support for qEEG as a noninvasive biomarker of Alzheimer's treatment effect."

Cognition also announced that the last patient has been enrolled and treated in the second cohort of the Phase 2 SHINE (Synaptic Health and Improvement of Neurological Function with Elayta) Study. This trial enrolled 62 adults with mild-to-moderate Alzheimer's disease who were randomized to receive CT1812 (Elayta) in oral doses of 100 or 300 mg per day or placebo for six months. SHINE enrollment was lower than initially expected due to the introduction of protocol amendments designed to increase clinical assessments.

Anthony Caggiano, M.D., Ph.D., Cognition's chief medical officer, stated, "The first SHINE cohort of 24 patients yielded interesting findings, including a trend towards cognitive improvement in drug-treated compared to placebo-treated participants. We are looking forward to learning if this trend is replicated in the second cohort, which would offer valuable validation of the drug's mechanism. In addition, we are evaluating options for extending the protocol to add statistical power."

CT1812 is a brain-penetrant small molecule drug that binds to a receptor on neurons that regulates cellular damage response pathways, which are dysregulated in neurological diseases like Alzheimer's disease. By so doing, CT1812 displaces Aβ oligomers from the neuronal receptors where they bind, potentially allowing a cell's damage response mechanisms to return to normal function. CT1812 protects neurons against further binding of these oligomers, thus preventing the synapse damage and loss characteristic of Alzheimer's disease.

"These two clinical milestones are evidence of our continued progress in the advancement of CT1812 for neurodegenerative diseases," concluded Lisa Ricciardi, Cognition's president and CEO. "Looking forward, we expect that 2021 will be a transformational year for Cognition. In addition to concluding enrollment in the SEQUEL trial, we expect to have results from our SNAP study and to advance CT1812 into a large Phase 2 efficacy study in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC), which is funded by a sizable grant from the National Institute of Aging. We also expect to expand our pipeline candidates into additional neurodegeneration and neuro-ophthalmic indications, broadening the reach of our science into unmet clinical areas. I look forward to providing updates on all of these clinical milestones in the months ahead."

About the SEQUEL (COG0202) Study
Sixteen adults with mild-to-moderate Alzheimer's disease (MMSE 18-26) will be enrolled in the SEQUEL Study and will be randomized to receive either CT1812 or placebo once daily for 28 days (period 1). After a 14-day wash-out period, participants will then cross over into the other treatment arm for an additional 28 days (period 2). It is anticipated that patient enrollment will conclude by the end of 2021. Performance of qEEG and measurement of CSF biomarkers and cognitive performance will occur at baseline and after periods 1 and 2. The SEQUEL Study is funded by a $3.3 million grant from the National Institute on Aging of the NIH under award number R01AG058710.

About the SHINE (COG0201) Study
Sixty-two adults with mild-to-moderate Alzheimer's disease (MMSE 18-26) were enrolled in the SHINE Study, a randomized, double-blind, placebo-controlled, parallel-group Phase 2 study. The study was conducted in two parts. Part A enrolled 24 adults who received CT1812 in oral doses of 100 or 300 mg per day or placebo for 6 months. Part B randomized an additional 38 individuals into the study with the same design, doses and study duration. Safety, cognitive performance and biomarkers were measured at baseline and after 6 months of treatment. The SHINE Study was funded by a $16.6 million grant from the National Institute on Aging of the NIH under award number R01AG058660.

About Cognition Therapeutics, Inc.
Cognition Therapeutics, Inc. has discovered and is developing a pipeline of novel, disease-modifying, oral drug candidates to treat a broad array of neurodegenerative and neuro-ophthalmic disorders. Our pipeline compounds uniquely target the σ-2 receptor, a key regulator of the cellular damage response. CT1812, our lead product candidate, is being assessed in a comprehensive clinical program for Alzheimer's disease, including a 540-person Phase 2 study in collaboration with ACTC and supported by a competitive grant from the National Institute on Aging. Additional information about Cognition and its product candidates may be found online at www.cogrx.com.

Forward-Looking Statements
This press release contains "forward-looking statements" concerning the development and commercialization of Cognition's products, the potential benefits and attributes of such products, and Cognition's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Cognition undertakes no obligation to update any forward-looking statements for any reason.

CT1812 (Elayta™) is an investigational product and neither its use nor the tradename has been approved by the FDA.