



Cortexyme Announces European Screening Now Underway in the Phase 2/3 GAIN Trial

September 26, 2019

- International study is evaluating whether a new investigational medicine targeting *P. gingivalis* bacteria can slow or halt the progression of Alzheimer's disease

- GAIN Trial opened for U.S. enrollment in Q2 2019 and is expected to include approximately 90 sites globally

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 26, 2019-- Cortexyme, Inc. (Nasdaq: CRTX), a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's and other degenerative diseases, today announced the start of screening in Europe for the GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) Trial, the company's ongoing Phase 2/3 clinical study of lead investigational medicine COR388 in subjects with mild to moderate Alzheimer's disease (AD). The international trial has been enrolling in the United States since the second quarter of 2019 and is targeting enrollment of approximately 570 subjects. Potential participants and their caregivers can learn more about the trial at www.GAINtrial.com.

"Based upon our evidence to date, the GAIN Trial was designed to assess the safety and efficacy of COR388 against an upstream target of neurodegeneration, which we believe is foundational to addressing Alzheimer's disease," said Michael Detke, M.D., Ph.D., Cortexyme's chief medical officer. "We are excited to further examine the role gingipains play in the development of Alzheimer's disease, and whether targeting these toxic proteases can slow or stop disease progression."

The GAIN Trial is based on the growing body of scientific evidence that the bacterium most commonly associated with chronic periodontal disease, *Porphyromonas gingivalis*, plays a key role in the development of AD, given its identification in the brains of AD patients and ability to cause neurodegeneration, inflammation, and other pathology associated with Alzheimer's in animal models. The trial evaluates the ability of COR388, an investigational medicine designed to inactivate the toxic proteases, or gingipains, released by the bacteria, to stop or slow further damage to brain cells. Prior clinical studies of COR388 showed the compound was well-tolerated and identified positive trends across biomarkers and cognitive tests in subjects with AD.

"We must leave no stone unturned in the search for an effective Alzheimer's therapeutic, and the data to support testing COR388 is compelling," said Bruno Vellas, M.D., Ph.D., head of the Alzheimer Disease Clinical Research Centre at the University of Toulouse. "We are glad to be a site for this important study and look forward to supporting the best path forward for patients."

About the GAIN Trial

The GAIN Trial is a Phase 2/3 randomized, double-blind, placebo-controlled study assessing the efficacy, safety, and tolerability of two dose levels of COR388 oral capsules in subjects with mild to moderate AD. Randomized participants enter a screening period of up to six weeks, a 48-week treatment period, and a safety follow-up period of an additional six weeks. The primary endpoint for the study is mean change in the Alzheimer's Disease Assessment Scale-Cognitive Subscale 11 (ADAS-Cog 11) from baseline to 48 weeks. Secondary and exploratory endpoints include change in Alzheimer's Disease Cooperative Study Group-Activities of Daily Living (ADCS-ADL), change in Clinical Dementia Rating-Sum of Boxes (CDR-SB), Winterlight Speech Assessment, cerebral spinal fluid biomarkers of infection, and other measures. Top-line results from the trial are anticipated in the fourth quarter of 2021. More information about the trial can be found at www.GAINtrial.com.

About Cortexyme, Inc.

Cortexyme (Nasdaq: CRTX) is a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's disease and other degenerative diseases. Cortexyme is targeting a specific, infectious pathogen found in the brain of Alzheimer's patients and tied to neurodegeneration and neuroinflammation in animal models. The company's lead investigational medicine, COR388, is the subject of the GAIN Trial, an ongoing Phase 2/3 clinical study in patients with mild to moderate Alzheimer's. To learn more about Cortexyme, visit www.cortexyme.com or follow @Cortexyme on Twitter.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words. Forward-looking statements are based on Cortexyme's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties described in the section titled "Risk Factors" in the final prospectus related to Cortexyme's initial public offering filed with the Securities and Exchange Commission on May 9, 2019 and Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on June 12, 2019. Forward-looking statements contained in this press release are made as of this date, and Cortexyme undertakes no duty to update such information except as required under applicable law.

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