Cortexyme Announces Gain Trial in Alzheimer's Disease Has Reached Enrollment Milestone of 300 Patients

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- Sub-study shows greater than 90% of enrolled patients have moderate to severe periodontal disease, indicating relevance to mechanism of action against P. gingivalis

- Interim analysis of the Phase 2/3 GAIN Trial expected to occur before year-end 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Cortexyme, Inc. (Nasdaq: CRTX) today announced that enrollment in its GAIN Trial for Alzheimer's disease has reached 300 patients toward the study's previously announced enrollment target of 570 subjects. GAIN is a randomized, double-blind, placebo-controlled Phase 2/3 trial of COR388, Cortexyme's lead investigational medicine, in patients with mild to moderate Alzheimer's disease. GAIN's protocol includes an interim analysis for overwhelming efficacy on its co-primary cognitive and functional endpoints after 300 patients reach six months of treatment; this interim analysis is expected to occur before year-end 2020. Top-line results from the GAIN Trial's final analysis, to be performed once all study subjects complete one year of treatment, are expected in Q4 2021.

The target of COR388, gingipains produced by *P. gingivalis*, have been discovered in the brain of Alzheimer's patients and shown to produce Alzheimer's pathology in infected animals. *P. gingivalis* is best known as a keystone bacterium in the development of periodontal disease. The GAIN Trial includes a periodontal sub-study, in which approximately 40% of GAIN Trial participants are also assessed for endpoints of efficacy in periodontal disease. The GAIN Trial and the sub-study did not specify inclusion criteria related to periodontal status, and yet greater than 90% of patients enrolled had moderate to severe periodontal disease at baseline.

"We are pleased with the high level of engagement of our clinical sites and study participants, as well as with the operational execution of our team," said Michael Detke, M.D., Ph.D., Cortexyme's chief medical officer. "The pace of enrollment in the GAIN Trial reflects the need for new therapeutic options for patients with Alzheimer's disease and the interest in our upstream mechanism of action. We believe we are enrolling the right patients at the right time and we look forward to presenting study results when available."

For more information about the GAIN Trial, visit www.GAINtrial.com.

About the GAIN Trial

The GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) Trial is a randomized, double-blind, placebo-controlled Phase 2/3 trial evaluating the efficacy, safety, and tolerability of COR388, Cortexyme's investigational gingipain inhibitor, in patients with mild to moderate Alzheimer's disease. The GAIN Trial also includes a sub-study measuring the efficacy of COR388 on symptoms of periodontal disease including gingival pocket depth. The GAIN Trial has been enrolling since the second quarter of 2019, with top-line results from the study's final analysis expected in the fourth quarter of 2021. For more information on the trial, visit www.gaintrial.com.

About Cortexyme

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. Examples of forward-looking statements include, among others, statements we make regarding the timing and success of our clinical trials and related data, the timing of announcements and updates relating to our clinical trials and related data, the timing of and our ability to enroll patients into our clinical trials, and the potential therapeutic benefits, safety and efficacy of our product candidate. Forward-looking statements are based on Cortexyme's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and could cause actual results to differ materially from what we expect. 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, Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2019 and other reports as filed with the SEC. 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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