



Cortexyme Presents New Data Demonstrating Evidence of *P. Gingivalis* Infection of the Central Nervous System in Alzheimer's Disease at Annual Biomarkers for Alzheimer's Disease Summit

August 25, 2021

*GAIN Trial analysis of anti-*P. gingivalis* antibodies in cerebrospinal fluid supports upstream role of pathogenic bacterium in key Alzheimer's pathologies*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 25, 2021-- Cortexyme, Inc. (Nasdaq: CRTX), a company advancing a pivotal trial in Alzheimer's disease with top-line data expected by mid-November 2021 and a growing pipeline of therapeutics for degenerative diseases, announced the presentation of new data demonstrating evidence of *P. gingivalis* infection of the central nervous system in Alzheimer's disease at the [Annual Biomarkers for Alzheimer's Disease Summit](#), taking place virtually on Wednesday, August 25, 2021, at 2:10 p.m. ET followed by a live Q&A at 3:40 p.m. ET.

In a featured speaker presentation titled "Use of Novel Biomarkers of *P. Gingivalis* Infection & Neuroinflammation in the GAIN Trial: An Ongoing Phase 2/3 Clinical Trial Assessing the Activity of Atuzaginstat in Patients with Mild to Moderate Alzheimer's Disease," Cortexyme's Executive Vice President of Research and Development Leslie Holsinger, Ph.D., will present an analysis of anti-*P. gingivalis* antibodies in cerebrospinal fluid (CSF) with results demonstrating that:

- All patients analyzed at baseline in the GAIN Trial (472 out of 472 baseline CSF samples available) were positive for anti-*P. gingivalis* antibodies (IgG) in their cerebrospinal fluid;
- Less than 2% of patients analyzed had a leaky blood brain barrier, as defined by an albumin index greater than 9; and
- Anti-*P. gingivalis* IgG in the CSF was only very weakly correlated to the albumin index ($r=0.22$), indicating production in the central nervous system in addition to that shown previously in serum.

These data add to the growing body of evidence indicating the presence of a *P. gingivalis* infection within the central nervous system in patients with Alzheimer's disease. Cortexyme will also present other novel biomarkers developed to track markers of *P. gingivalis* and Alzheimer's disease, in addition to highlighting the upstream role that *P. gingivalis* plays in key pathologies of Alzheimer's disease progression. The complete presentation will be available [here](#).

About The GAIN Trial

Cortexyme is pioneering an innovative, upstream, and disease-modifying therapeutic approach to Alzheimer's disease. The Phase 2/3 GAIN Trial is a pivotal study in 643 patients with mild to moderate Alzheimer's Disease. Cortexyme's seminal discovery, along with confirmatory clinical and preclinical studies, demonstrate that the intracellular pathogen, *P. gingivalis*, is found in the brain of more than 90% of Alzheimer's patients and that an oral infection with *P. gingivalis* in animals results in brain infiltration and downstream hallmark Alzheimer's pathologies, including A β 2 production, tau hyperphosphorylation, microglial activation, and neurodegeneration. The company's lead drug candidate, atuzaginstat (COR388), is a first-in-class, orally administered, brain penetrant small molecule targeting *P. gingivalis*, which is upstream of neuronal death and Alzheimer's disease pathology. Atuzaginstat blocks gingipains, protease virulence factors secreted by *P. gingivalis*, which are required for its survival and responsible for its toxicity. The GAIN Trial also includes a REPAIR sub-study of 233 patients targeting *P. gingivalis* – a keystone bacterium associated with periodontal disease – and measuring the efficacy of atuzaginstat on clinical endpoints of periodontal disease. Cortexyme's innovative therapeutic approach continues to be supported by research from laboratories around the world published in peer-reviewed scientific journals.

About Cortexyme

Cortexyme, Inc. (Nasdaq: CRTX) is a clinical stage biopharmaceutical company pioneering upstream therapeutic approaches designed to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. The company is advancing its disease-modifying pivotal GAIN Trial in mild to moderate Alzheimer's disease with top-line data expected by mid-November 2021, in addition to growing a proprietary pipeline of first-in-class small molecule therapeutics for Parkinson's disease, periodontitis, and other diseases with high unmet clinical need. Cortexyme's lead program targets a specific, infectious pathogen called *P. gingivalis* found in the brain and other organs and tied to degeneration and inflammation in humans and animal models. The company's causation evidence for Alzheimer's disease and the mechanism of its novel therapeutic has been independently replicated and confirmed by multiple laboratories around the world, as well as published in peer-reviewed scientific journals. To learn more about Cortexyme, visit www.cortexyme.com or follow @Cortexyme on Twitter.

Forward-Looking Statements

Statements in this news release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this news release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast," "potential" or other similar words. Examples of forward-looking statements include, among others, statements Cortexyme makes regarding the sufficiency of its cash position to fund its operations; its business plans, strategy, timeline, prospects, and milestone expectations; the timing and success of the company's clinical trials and related data, including with respect to the GAIN and REPAIR Trials, as well as enabling and human studies of COR588; the potential of atuzaginstat to treat Alzheimer's disease, periodontal disease, and other potential indications; the potential of COR803 to treat coronavirus infections; the timing of announcements and updates relating to its clinical trials and related data; the potential therapeutic benefits, safety and efficacy of the company's product candidate or library of compounds and statements about its ability to obtain, and the timing relating to, regulatory submissions and approvals with respect to the company's drug 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 the company expects. 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 Cortexyme's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 1, 2021, its Quarterly Report on Form 10-Q filed with the SEC on August 6, 2021, and other reports as filed with the SEC. Forward-looking statements contained in this news 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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