



Cortexyme Presents Updated Baseline Data from Complete Set of Participants Enrolled in Pivotal GAIN Trial at ASCP 2021 Annual Meeting

June 1, 2021

Baseline demographic and biomarker data reinforce appropriate patient population enrolled ahead of top-line data expected in fourth quarter 2021

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 1, 2021-- Cortexyme, Inc. (Nasdaq: CRTX), a company advancing a pivotal trial in Alzheimer's disease with topline data expected in the fourth quarter of 2021 and a growing pipeline of therapeutics for degenerative diseases, announced the presentation of updated baseline demographic and biomarker data at the American Society of Clinical Psychopharmacology (ASCP) 2021 Annual Meeting.

Reflecting the complete set of baseline samples available from 643 GAIN study participants, including 233 individuals in the trial's REPAIR periodontal sub-study, key findings reported in today's presentation, titled "An Update and Baseline Data from the Phase 2/3 Gain Trial of COR388 (Atuzaginstat) a Novel Bacterial Virulence Factor Inhibitor for the Treatment of Alzheimer's Disease," include:

- 84% of participants have an A β 42/40 cerebral spinal fluid (CSF) ratio associated with A β positivity on PET scan.
- 88% of subjects have total Tau CSF levels consistent with AD.
- 84% have pTau 181 levels consistent with AD in the Amyloid/Tau/Neurodegeneration (ATN) designation.
- All subjects had evidence of *P. gingivalis*-specific IgG at baseline, with 78% exhibiting higher antibody titers associated with periodontal disease. (Offenbacher et al., 2007)
- Previous research has demonstrated that IgG titers roughly correlate to infection load. (Kojima et al., 1997)
- More than 90% of participants in the REPAIR periodontal sub-study have moderate to severe periodontal disease at baseline.
- 64% of the trial participants carry at least one ApoE4 gene and these participants are stratified across the three treatment groups.

The data (Abstract #3002870) are being presented in an oral session at the ASCP 2021 Annual Meeting today, as well as in a poster session tomorrow, June 2, 2021, as a part of this virtual event. Baseline biomarker data analyses presented at ASCP include 100% of the enrolled subjects with baseline CSF or serum samples available for analysis. The presentation and poster with additional detail will be available at <https://ir.cortexyme.com/news-and-events/presentations>.

Cortexyme's ongoing pivotal Phase 2/3 GAIN Trial is rooted in a strong body of research outlining the role of *P. gingivalis* in the neurodegeneration associated with AD. *P. gingivalis*, which is most commonly associated with periodontal disease, has been discovered in greater than 90% of post-mortem brains of patients with AD and has been shown to produce Alzheimer's pathology in infected animals. The GAIN Trial is evaluating the potential of Cortexyme's lead compound, atuzaginstat, to inhibit the toxic proteases, or gingipains, produced by *P. gingivalis* in patients with mild to moderate AD and to potentially slow or halt AD progression. The trial has completed enrollment, and 643 subjects have been randomized to one of two doses of atuzaginstat (40mg or 80mg twice daily) or placebo. The co-primary endpoints are mean change in cognition (ADAS-Cog 11) and function (ADCS-ADL) from baseline to 48 weeks compared to placebo. Secondary and exploratory endpoints include change in Winterlight Speech Assessment, cerebral spinal fluid biomarkers, volumetric MRI, and other measures. The GAIN Trial also includes a REPAIR sub-study measuring the efficacy of COR388 on symptoms of periodontal disease, including gingival pocket depth.

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 in the fourth quarter of 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," or other similar words. Examples of forward-looking statements include, among others, statements we make regarding our 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; the potential of atuzaginstat to treat Alzheimer's disease, periodontal disease, and other potential indications; its ability to fund planned operating and capital expenditures; the timing of announcements and updates relating to its clinical trials and related data; the timing of and its ability to enroll patients into its clinical trials; the potential therapeutic benefits, safety and efficacy of the company's product candidate or library of compounds; statements about its ability to obtain, and the timing relating to, regulatory submissions and approvals with respect to the company's drug product candidate; and expected cash runway and financial update. 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 May 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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Cortexyme Contact:

Stacy Roughan
Cortexyme, Inc.
Vice President, Corporate Communications & Investor Relations
ir@cortexyme.com

Media Contact:

Hal Mackins
Torch Communications, LLC
hal@torchcomllc.com
415-994-0040

Investor Contact:

Corey Davis, Ph.D.
LifeSci Advisors
cdavis@lifesciadvisors.com
212-915-2577

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