Cortexyme Announces Clinical Hold on Atuzaginstat's Investigational New Drug Application

January 26, 2022

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 26, 2022-- Cortexyme, Inc. (Nasdaq: CRTX), a clinical-stage biopharmaceutical company focused on Alzheimer's and other degenerative diseases, today announced that the company received a letter from the U.S. Food and Drug Administration (FDA) on January 25, 2022 placing a full clinical hold on atuzaginstat's (COR388) Investigational New Drug application (IND 134303). The company plans to provide additional updates pending continued engagement with FDA.

Cortexyme is immediately implementing a cost reduction program to rationalize operations and to allow continued support for planned clinical milestones, providing an expected cash runway through 2024. The company intends to prioritize development of its next generation gingipain inhibitor, COR588, in Alzheimer's disease. COR588 is currently completing a Phase 1 SAD/MAD study and results are expected in the second quarter 2022. In addition, Cortexyme plans to explore strategic alternatives for its coronavirus program and non-Alzheimer's indications for COR388. Cortexyme intends to provide a more detailed update on its pipeline and anticipated milestones for 2022 in the near future.

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. Cortexyme's lead program targets a specific, infectious pathogen called *P. gingivalis* found in the brain of Alzheimer's patients 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," "plans," "intends," "will," "may," "should," "estimate," "project," "outlook," "runway," "forecast," "potential" or other similar words. Examples of forward-looking statements include, among others, the strategic development path for atuzaginstat, including with respect to COR388, COR588, and other programs and indications; its business plans, pipeline, strategy, planned clinical trials and timeline, prospects, and milestone expectations; the expected cash runway; the timing and success of the company's clinical trials and related data, including plans and the ability to conduct and/or complete current and additional studies, including the Phase 1 SAD/MAD study; the implementation of cost reduction measures; the potential of atuzaginstat to treat Alzheimer's disease and other indications; 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, further development of atuzaginstat, regulatory submissions and interactions with regulators, and related response and decisions, including with respect to the company's full clinical hold, 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 October 29, 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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Source: Cortexyme, Inc.