Cortexyme Successfully Completes Phase 1 Single and Multiple Ascending Dose Clinical Trial of COR588

July 27, 2022

Once daily dose of COR588 over 10-day period well-tolerated with no serious adverse events observed

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 27, 2022-- Cortexyme, Inc. (Nasdaq: CRTX), a clinical-stage biopharmaceutical company focused on advancing therapeutics for rare and degenerative diseases, today reported the successful completion of its Phase 1 single ascending dose and multiple ascending dose (SAD/MAD) clinical trial of COR588, the company's lysine gingipain inhibitor in development for the treatment of Alzheimer's disease and indications with disease pathology associated with the keystone pathogen *P. gingivalis*. The study was a randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, and pharmacokinetics of COR588 in healthy adult participants.

Previously announced in March 2022, the SAD portion of the Phase 1 clinical trial demonstrated that COR588 was well-tolerated across all cohorts in the dose range from 25 mg to 200 mg with no serious adverse events. No clinically significant findings were observed on safety measures, including vital signs, laboratory findings, telemetry, or ECGs. No clinical chemistry or hematology safety concerns were observed at any dose. Additionally, COR588 exhibited an 11-to-12-hour half-life consistent with once daily dosing and a dose-proportional pharmacokinetic profile that importantly achieved the targeted exposure predicted for therapeutic efficacy.

The MAD portion of the Phase 1 clinical trial of COR588 demonstrated that once daily oral administration of COR588 over a 10-day period was well-tolerated across all cohorts in the dose range from 50 mg to 200 mg with no serious adverse events observed. High central nervous system penetration of COR588 was confirmed after 10 days of administration.

Cortexyme will provide an update on the development path forward for COR588 in conjunction with its planned corporate name change to Quince Therapeutics and detailed go-forward growth strategy that is expected to be announced on August 1, 2022.

About COR588

COR588 is a selective, oral small-molecule inhibitor of lysine gingipains, protease virulence factors secreted by *P. gingivalis,* and is being developed for the potential treatment of patients with Alzheimer's disease. Sponsored by Cortexyme, the COR588 Phase 1 clinical trial (Identifier: NCT04920903) was a randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of oral COR588 capsules in healthy adult participants.

About Cortexyme

Cortexyme, Inc. (Nasdaq: CRTX) is a clinical stage biopharmaceutical company focused on advancing therapeutics for rare and degenerative diseases. The company's innovative pipeline includes a precision bone growth molecule and drug-targeting platform to treat rare skeletal diseases, bone cancer and injury, in addition to small molecule therapeutics targeting the infectious pathogen *P. gingivalis*' role in degenerative disease progression, including indications such as periodontal disease, oral potentially malignant disorders, squamous cell carcinoma, and Alzheimer's disease, among others. 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," "will," "may," "should," "estimate," "project," "potential," "encouraged," or other similar words. Examples of forward-looking statements include, among others, the strategic development path for COR588; its business plans, internal and external development of the pipeline, strategy; the timing and success of the company's clinical trials and related data, including plans and the ability to initiate, conduct and/or complete current and additional studies; the potential of the company's COR588 to treat Alzheimer's disease and other indications; and the potential therapeutic benefits, safety and efficacy of the company's product candidate or library of compounds. 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, 2022, its Quarterly Report on Form 10-Q filed with the SEC on May 10, 2022, 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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