Revive Therapeutics Provides Update on FDA Phase 3 Clinical Trial for Bucillamine in COVID-19 with Planned Completion and Emergency Use Authorization Request

TORONTO, Feb. 26, 2021 (GLOBE NEWSWIRE) -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (CSE: RVV, USA: RVVTF), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, is pleased to announce an update on the Company’s U.S. Food & Drug Administration (“FDA”) Phase 3 clinical trial (the “Study”) to evaluate the safety and efficacy of Bucillamine in patients with mild to moderate COVID-19.

With its recent $23 million dollar financing, the Company plans to aggressively expand from 14 clinical sites to up to 50 clinical sites to meet the next enrollment goals for the Study in Q2-2020. The Study is a randomized, double-blinded, placebo-controlled trial and the safety and efficacy data analyzed at each interim analysis timepoint of 210, 400, 600 and 800 completed patients are only made available to the Independent Data and Safety Monitoring Board (“DSMB”) for review and recommendations on continuation, stopping or changes to the conduct of the Study. In the event of any serious safety concerns, the DSMB would be notified to determine any risks and provide its recommendations. To date, in this initial 210 interim point there have been no serious safety concerns that required the DSMB to be notified.

Further to the DSMB review and recommendations on each interim analysis periods, the Company aims to approach the FDA to obtain agreement on filing an Emergency Use Authorization (“EUA”) for Bucillamine to treat mild to moderate COVID-19.

“With our funding completed we are adding more clinical sites to meet our enrollment goals and be in a position to meet with the FDA to determine the best path forward for EUA approval,” said Michael Frank, CEO of Revive. “We are committed to achieving our mission in making Bucillamine the first orally administered drug to obtain FDA approval and EUA to treat mild to moderate COVID-19.”

About the Phase 3 Clinical Trial (ClinicalTrials.gov Identifier: NCT04504734)

The Phase 3 confirmatory clinical trial titled, “A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Bucillamine in Patients with Mild-Moderate COVID-19”, will enroll up to 1,000 patients that will be randomized to either Bucillamine or placebo for up to 14 days. The primary objective is to compare the frequency of hospitalization or death in patients with mild-moderate COVID-19 receiving Bucillamine with those receiving placebo. The primary endpoint is the proportion of patients meeting a composite endpoint of hospitalization or death from the time of the first dose through Day 28 following randomization. Efficacy will be assessed by comparing clinical outcomes (death or hospitalization), disease severity using the 8-category NIAID COVID ordinal scale, supplemental oxygen use, and progression of COVID-19 between patients receiving standard-of-care plus Bucillamine and patients receiving standard-of-care plus placebo. Safety will be assessed by reported pre-treatment adverse events and treatment-emergent adverse events (including serious adverse events and adverse events of special interest), laboratory values (hematology and serum chemistry), vital signs (heart rate, respiratory rate, and temperature), and peripheral oxygen saturation.

The Company is not making any express or implied claims that its product has the ability to eliminate or cure COVID-19 (SARS-2 Coronavirus) at this time.

About Revive Therapeutics Ltd.

Revive is a life sciences company focused on the research and development of therapeutics for infectious diseases and rare disorders, and it is prioritizing drug development efforts to take advantage of several regulatory incentives awarded by the FDA such as Orphan Drug, Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of infectious diseases, with an initial focus on severe influenza and COVID-19. With its recent acquisition of Psilocin Pharma Corp., Revive is advancing the development of Psilocybin-based therapeutics in various diseases and disorders. Revive’s cannabinoid pharmaceutical portfolio focuses on rare inflammatory diseases and the company was granted FDA orphan drug status designation for the use of Cannabidiol (CBD) to treat autoimmune hepatitis (liver disease) and to treat ischemia and reperfusion injury from organ transplantation. For more information, visit www.ReviveThera.com.

For more information, please contact:

Michael Frank
Chief Executive Officer
Revive Therapeutics Ltd.
Tel: 1 888 901 0036
Email: mfrank@revivethera.com
Website: www.revivethera.com

Cautionary Statement

This press release contains 'forward-looking information' within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words "could", "intend", "expect", "believe", "will", "projected", "estimated" and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on Revive's current belief or assumptions as to the outcome and timing of such future events. Forward looking information in this press release includes information with respect to the Company's cannabinoids, psychedelics and infectious diseases programs. Forward-looking information is based on reasonable assumptions that have been made by Revive at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Revive is not obligated to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable securities laws. The foregoing statements expressly qualify any forward-looking information contained herein. Reference is made to the risk factors disclosed under the heading "Risk Factors" in the Company's annual MD&A for the fiscal year ended June 30, 2020, which has been filed on SEDAR and is available under the Company's profile at www.sedar.com.