Revive Therapeutics Provides Update on FDA Phase 3 Clinical Trial for Bucillamine in COVID-19

- *DSMB support in continuing the Phase 3 clinical trial; No serious adverse events and safety concerns reported to date.*
- *Phase 3 clinical trial to incorporate viral load testing for a minimum of 300 patients.*
- *Finalizing key research of thiol-based drugs, including Bucillamine, against the Delta variant of COVID-19.*
- *Engaged 46 clinical sites to date to complete the Phase 3 clinical trial.*
- *Expect to complete enrollment in Q4-2021.*
- *Finalizing global manufacturing capabilities to support the production of at least 5 billion Bucillamine tablets for global commercialization in 2022.*

TORONTO, Oct. 26, 2021 (GLOBE NEWSWIRE) -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (OTCQB: RVVTF) (CSE: RVV) (FRANKFURT:31R), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, is pleased to provide 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.

The Study is a randomized, double-blinded, placebo-controlled trial and the safety and efficacy data at each interim analysis timepoint, in which the final interim analysis will be at 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.

The DSMB supported continuation of the Study in its last meeting as there was no serious adverse events or safety concerns reported and it is expected that the final interim analysis meeting, which will take place at 800 completed patients to be held in Q4-2021.

In light of the spread of the Delta variant of COVID-19 and as a follow on to a recent study, titled “Thiol-based drugs decrease binding of SARS-CoV-2 spike protein to its receptor and inhibit SARS-CoV-2 cell entry”[1] showing that thiol-based drugs, like Bucillamine, decrease the binding of SARS-CoV-2 spike protein to its receptor, decrease the entry efficiency of SARS-CoV-2 spike pseudotyped virus, and inhibit SARS-CoV-2 live virus infection, the Company supported research under its sponsored agreement with the University of California, San Francisco (“UCSF”) in the laboratory of Dr. John Fahy to explore the utility of thiol-based drugs, including Bucillamine, against the Delta variant of COVID-19. Research results will be made available via a publication shortly.

As a result of the research and the rise of the Delta variant of COVID-19, the Company has also decided to incorporate viral load testing to complement the Study to a minimum of 300 patients that will be enrolled in the Study. The viral load will allow the Company to quantify the speed in which Bucillamine can reduce viral infection of patients throughout the course of treatment, thus allowing to understand the most optimal time to introduce Bucillamine in the treatment course and provide confidence in the potential utility and effectiveness of Bucillamine in COVID-19.

The Company currently has engaged a total of 46 clinical sites in fourteen states including: Alabama, Arkansas, California, Florida, Georgia, Illinois, Michigan, Nevada, New York, North Carolina, Ohio, South Carolina, Tennessee and Texas. Also one clinical site in Puerto Rico.

The Company expects to eventually file an Emergency Use Authorization (“EUA”) with the FDA in the event that the blinded results provide evidence to the DSMB’s final review to recommend to pursue EUA for Bucillamine to treat mild to moderate COVID-19.

In addition, the Company is in discussions with its manufacturing partner to secure commercial supply of at least 5 billion Bucillamine tablets to potentially treat at least 50 million people globally for 2022.

The Company is continuing discussions with reputable international pharmaceutical companies seeking to obtain commercial rights to Bucillamine as a treatment for COVID-19 in various countries in Europe, India and Asia. In light of these discussions, Revive is pursuing a commercialization plan that would leverage the clinical results from the U.S. Phase 3 study to allow for drug approvals globally.

Michael Frank, CEO of the Company commented, “As we move forward in our Phase 3 study in COVID-19 with the aim to seek EUA approval from the FDA for Bucillamine in the treatment of mild to moderate COVID-19, we are also cognizant of the rapidly changing landscape of COVID-19 specifically with the Delta variant becoming widespread. The incorporation of adding viral load testing to patients in the Study, along with our support in the research of the potential utility of thiol-based drugs, like Bucillamine, in the Delta variant of COVID-19, shows our confidence in Bucillamine’s potential as a safe and effective oral treatment for mild to moderate COVID-19. We recognize the market opportunity for Bucillamine and we are in discussions with our manufacturing partners to ensure that billions of Bucillamine tablets can be made available in 2022 to support our future commercialization partners and the millions of people globally.”

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 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 therapy 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 (high dose and/or low dose) 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 independent DSMB will actively monitor interim data for the ongoing safety of patients and will recommend continuation, stopping or changes to the conduct of the study based on the interim analysis reports.

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 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.

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Sources:

1. https://www.biorxiv.org/content/10.1101/2020.12.08.415505v1