Revive Therapeutics Provides Update From Type C Meeting with FDA for Amended Protocol Agreement of Phase 3 Clinical Study for Bucillamine in the Treatment of COVID-19

FDA recommends additional revised primary symptom-based endpoints

Revive to provide amended statistical analysis plan to support unblinding of the data to potentially provide evidence of efficacy

TORONTO, March 08, 2023 -- 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, announces today an update on the Type C meeting written responses received by the Company from the U.S. Food & Drug Administration ("FDA") to obtain agreement on the proposed protocol endpoints for the Company's Phase 3 Study (the "Study") (NCT04504734) to evaluate the safety and efficacy of Bucillamine, an oral drug with anti-inflammatory and antiviral properties, in patients with mild to moderate COVID-19. The FDA recommends that the Company's proposed primary symptom-based endpoints should cover the evaluation of time to sustained recovery assessed over an appropriate duration, evidence of subjects experiencing resolution of COVID-19 related symptoms and the element of sustained symptom resolution. In addition, the FDA requires the Company to provide a revised statistical analysis plan (the "SAP") that incorporates the FDA recommendations of the proposed primary symptom-based endpoints for the Study and outlines how symptoms are assessed and with what frequency, how improvement will be defined, and how the endpoint will be analyzed. The Company's proposed secondary endpoints can also be included in the Study to assess the impact of treatment on how a patient feels, functions, or survives.

As a result of the FDA responses from the Type C meeting, the Company plans to amend the SAP and Study protocol incorporating the suggestions of the FDA. Once the FDA accepts the revised SAP and Study protocol, the Data Safety Monitoring Board ("DSMB") will review the Study's completed blinded Post-Dose selection data of approximately 500 subjects in accordance with the accepted Study protocol. The DSMB may recommend continuing the Study if there is a trend toward achieving statistical significance, halting the Study early due to statistical significance likely not going to be met, or halting the Study early due to positive efficacy showing statistical significance. Depending on the outcome of the DSMB review, the Company could proceed to unblind the data and request a meeting with the FDA to review the data providing evidence of the potential efficacy of Bucillamine for COVID-19 and determine the next steps. The Company may also pursue additional studies with Bucillamine for Long COVID or COVID-related conditions, and various infectious and respiratory disorders should the data from the Study prove worthwhile.

The Study's proposed primary symptom-based endpoints are partly due to the evolving and current state of COVID-19, where many patients with COVID-19 are either asymptomatic or experience mild to moderate illness and could be managed in the outpatient setting. Patients who would have been at increased risk for progression to severe COVID-19 or require hospitalization during the various variant surges are now being managed less aggressively as outpatients, with close follow-up and monitoring for clinical changes. Based on Bucillamine's proposed mode of action, it is believed that the speed of symptom resolution and reduced viral shedding, if given promptly, could help mitigate the disease burden globally.

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.

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

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