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

- *Phase 3 clinical trial ongoing with next DSMB meeting at 600 completed patients.*
- *Currently at 41 clinical sites and to engage a minimum of 50 clinical sites.*
- *Aim to complete enrollment in Q3-2021 and FDA EUA submission in late-Q3/Q4-2021.*
- *Preparing commercial activities for international drug approvals.*

TORONTO, July 15, 2021 -- 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-blind, placebo-controlled trial and the safety and efficacy data at each remaining interim analysis timepoint, which currently are 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.

The next DSMB meetings will take place at 600 and 800 completed patients, which are expected to be held in Q3-2021. The Company is continuing the Phase 3 clinical trial with the recent recommended 600 mg high dose as selected by the DSMB.

To date, the ongoing Study has not seen any serious adverse events or safety concerns that required the DSMB to be notified or take action on. In the event of any serious safety concerns, the DSMB would be notified to determine any risks and provide its recommendations.

The Company currently has partnered with 40 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. Revive will continue to expand to a minimum of 50 clinical sites within the current states and in COVID-19 hot spot states.

Further to the DSMB review and recommendations on each interim analysis periods, the Company is preparing for the potential of filing an Emergency Use Authorization ("EUA") with the FDA in the event that the blinded results provide evidence to the DSMB to recommend to pursue EUA for Bucillamine to treat mild to moderate COVID-19. The Company is on track to meet its planned enrollment goal for the Study in Q3-2021 and aim to file EUA with the FDA.

The Company is in 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, "We are pleased with the status of 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 patients. We have made tremendous progress over the last few months by engaging over 40 clinical sites and completing patient enrollment to meet its completed and future DSMB interim analysis timepoints which will allow for the Study to continue and to have potential to seek EUA approval from the FDA. We are continuing to add to our clinical site roster in the U.S. and patient enrollment that would expedite the completion of the Phase 3 study. Also, we are in discussions with international pharmaceutical companies seeking to obtain commercialization rights in various countries around the world."

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 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 Therapeutics Ltd. (OTCQB: RVVTF) (CSE: RVV) (FRANKFURT: 31R) is a biotech company focused on the research, development and commercialization of therapeutics for

infectious diseases and rare disorders, and psychedelics to treat mental health and substance abuse disorders. Revive prioritizes its drug development programs to take advantage of various regulatory incentives awarded by the FDA such as Orphan Drug, Fast Track and Breakthrough Therapy designations, as well as Emergency Use Authorizations. Currently, the Company is exploring the use of an oral drug, Bucillamine, for the potential treatment of infectious diseases, with an initial focus on COVID-19, which is currently being evaluated in an FDA Phase 3 clinical trial to treat mild to moderate COVID-19. The Company has a robust psychedelics pharmaceutical program with the development of an oral thin film strip delivering psilocybin to treat mental health and substance abuse disorders and advancing the novel use of psilocybin to treat traumatic brain injury and stroke. Revive's cannabinoid pharmaceutical portfolio focuses on rare inflammatory diseases and the Company was granted FDA orphan drug designation for the use of Cannabidiol to treat autoimmune hepatitis and to treat ischemia and reperfusion injury from organ transplantation. For more information, visit www.ReviveThera.com.

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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.