Revive Therapeutics Announces Filing of a Pre-CTA Meeting Request with Health Canada and Update on U.S. FDA IND Filing and Phase 3 Clinical Trial Design for Bucillamine in the Treatment of COVID-19

TORONTO, June 03, 2020 -- Revive Therapeutics Ltd. ("Revive" or the "Company") (CSE: RVV), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, is pleased to announce that it has filed its Clinical Trial Application ("Pre-CTA") with Health Canada and provides an update on the filing of its Investigational New Drug ("IND") package to the U.S. Food and Drug Administration ("FDA") for the proposed Phase 3 confirmatory clinical trial ("Phase 3 study") to evaluate Bucillamine in the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection.

"We are very pleased with the progress that has been made with our clinical strategy for Bucillamine in the potential treatment of COVID-19, specifically with our focus on a Phase 3 confirmatory study to be conducted in the U.S. and our expansion into Canada," said Michael Frank, Revive's Chief Executive Officer.

The Company will have its Pre-CTA meeting with Health Canada this week. A complete briefing package accompanied the meeting request to discuss Bucillamine's Chemistry, Manufacturing and Controls, non-clinical and clinical safety information, clinical trial design, and Health Canada's guidance regarding the possibility of including an additional exploratory arm in the proposed trial in a subset of patients from the pediatric population. Results from the Pre-CTA meeting with Health Canada will be made available and the Company expects to initiate a clinical study as soon as possible following receipt of regulatory clearance from Health Canada.

Additionally, Revive is finalizing its IND with the U.S. FDA for the proposed Phase 3 confirmatory clinical trial to evaluate Bucillamine in the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection. The Company will file the IND later this month and expects final approval to proceed to the Phase 3 study shortly thereafter.

Phase 3 Study Design

The Phase 3 study will be an adaptive design titled, A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Bucillamine or Placebo in Patients with Mild-Moderate COVID-19. Symptomatic patients will initially be randomized 1:1:1 to receive Bucillamine 300 mg/day, Bucillamine 600 mg/day, or placebo.

The Phase 3 study will enroll a minimum of 210 patients, then a single Bucillamine dose is selected and a go/no-go decision is made. Patients will then be randomized 2:1 to the selected Bucillamine dose and placebo. Interim analyses will occur every 100 subjects up to the maximum sample size of 800 people. An independent data safety monitoring board ("DSMB") will actively monitor interim data for the ongoing safety of patients.

The primary objective of the Phase 3 study is to compare frequency of hospitalization and mortality in patients with mild-moderate COVID-19 receiving Bucillamine therapy with those receiving placebo. The primary endpoint is a 3-level ordinal scale of a patient's worst outcome between randomization and day 28. The levels of the ordinal outcome are 1) death, 2) alive and hospitalized, and 3) alive and not hospitalized.

Secondary objectives will aim to evaluate the safety of Bucillamine therapy at low (300 mg/day) and high (600 mg/day) dose levels when administered up to 14 days; to compare disease course in patients with mild-moderate COVID-19 receiving Bucillamine therapy with those receiving placebo; to evaluate time to clinical improvement in patients with COVID- 19 receiving low- and high-dose Bucillamine compared with placebo; and to assess impact of Bucillamine therapy on supplemental oxygen needs of patients with COVID-19. In addition, an exploratory objective will be to evaluate the effects of Bucillamine on viral clearance from nasal swabs in patients with COVID-19.

The Company is not making any express or implied claims that its product has the ability to eliminate or cure COVID-19 (or SARS2 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 strains including 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**

Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

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 Offering, including the intended use of proceeds. 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, 2019, which has been filed on SEDAR and is available under the Company's profile at **www.sedar.com**.*