Revive Therapeutics Provides Update of Phase 3 Clinical Study for Bucillamine in the Treatment of COVID-19

TORONTO, May 12, 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, announced today an update on the Company’s U.S. Food & Drug Administration (“FDA”) Phase 3 clinical trial (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.

On May 10th, 2023, the independent Data Safety Monitoring Board (“DSMB”) met to review the Study’s Post-Dose selection data under the current Study’s protocol primary endpoint, the *proportion of patients meeting a composite endpoint of hospitalization or death from time of first dose through Day 28 following randomization*. The DSMB recommended that the Study be halted early due to statistical significance of the primary endpoint likely not going to be met should the Study continue towards completion. Based on the recommendation from the DSMB, the Company has halted the Study and will now proceed to unblind and seek an evaluation of the Study’s data, including the COVID-19 clinical symptoms data (i.e. cough, fever, heart rate, and oxygen saturation) to determine the potential next clinical and regulatory steps for Bucillamine. The Company believes that once it has completed the evaluation of the Study’s data, it could support further discussions with the FDA on potential new clinical studies and allow the opportunity to work with potential domestic and international pharmaceutical partners to determine a suitable regulatory pathway for approval of Bucillamine based on the evaluated Study’s data.

The Company is committed to advancing the clinical and commercial development of Bucillamine and plans to pursue the following activities:

1. Continue discussions with the FDA on a pathway for future potential clinical studies for regulatory approval under proposed new efficacy endpoints based on the evaluation of the Study’s data;
2. Work with interested pharmaceutical partners to pursue potential domestic and international regulatory approvals and new clinical studies for Long COVID or COVID symptom-related conditions and various infectious, inflammatory and respiratory disorders; and
3. Develop reformulation strategies of Bucillamine to expand on its potential therapeutic utility targeting rare disorders that may come with regulatory incentives awarded by the FDA, such as orphan drug (i.e. ischemia-reperfusion injury, cystinuria), fast track, and breakthrough therapy designations.

At this time, the Company will only provide regular updates via press releases as information becomes available.

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. There can be no assurance that the Company will proceed with the clinical development and regulatory approvals of Bucillamine for COVID-19 in the U.S. and internationally.

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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Neither the Canadian Securities Exchange nor its Regulation Services Provider has reviewed or accepts 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 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, 2022, which has been filed on SEDAR and is available under the Company's profile at www.sedar.com.