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

TORONTO, April 18, 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. Following the Type C meeting with the FDA, the Company has reviewed the current environment of new hospital admissions of patients with confirmed COVID-19 internationally and in the U.S., where it is steadily declining (Source: CDC), evaluated potential patient recruitment strategies, and discussed with potential pharmaceutical partners to pursue Bucillamine as a potential treatment for COVID-19.

After further regulatory discussions with various groups, the Company has now decided that it will have the Data Safety Monitoring Board (“DSMB”) review the Study’s Post-Dose selection data of approximately 500 subjects for efficacy. This will take place 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 may then 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. In the latter case, the Company would request a meeting with the FDA to determine the appropriate next steps toward obtaining potential regulatory approval. Should the DSMB recommend continuing the Study, the Company will then evaluate the current environment of COVID-19 and the likelihood of efficiently obtaining hospitalizations for the remainder of the Study and potentially bringing a pharmaceutical partner to support the continuation of the Study. Should the DSMB recommend not to pursue the Study due to statistical significance likely not going to be met, the Company will accept the DSMB decision and seek an evaluation of COVID-19 clinical symptoms data (i.e. cough, fever, heart rate, and oxygen saturation), which will support further discussions with the FDA and potential pharmaceutical partners to determine a suitable regulatory approval pathway for Bucillamine in the U.S. and internationally.

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 regulatory approval under the Study’s objectives or clinical symptoms data;
2. Work with interested pharmaceutical partners to pursue potential 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.

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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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.