Revive Therapeutics Submits Updated Briefing Package in Support of Upcoming Type C Meeting Granted by FDA for Amended Protocol Agreement of Phase 3 Clinical Study for Bucillamine in the Treatment of COVID-19

TORONTO, Jan. 19, 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 that it has submitted the updated briefing package to the U.S. Food & Drug Administration ("FDA") to include the rationale for the proposed primary and efficacy endpoints for the amended protocol in the treatment of COVID-19 and supporting new information and independent published studies, including the most recent published study, titled "Omicron Spike Protein Is Vulnerable to Reduction."

As recently reported by the Company, the FDA has granted the Company's Type C meeting request to obtain agreement on the revised protocol endpoints for the Company's 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. The goal date for the FDA to provide its written responses is March 7, 2023.

The Company previously submitted to the FDA the Study's amended protocol with the new primary efficacy endpoint, specifically, assessing the difference in the proportion of participants with improvement in at least two COVID-19 related clinical symptoms on or before Day 14 compared with baseline between bucillamine versus placebo. Additional secondary endpoints are considered, including the time to the polymerase chain reaction resolution, clinical outcome (death or hospitalization), disease severity, supplemental oxygen use, and progression of COVID-19.

Should the FDA agree with the Company's proposed primary and secondary endpoints or a version that the FDA recommends, the Company will incorporate these endpoints into the amended Study protocol. Once the amended Study protocol is agreed upon, the Data Safety Monitoring Board ("DSMB") will then review the completed Post-Dose selection data of approximately 500 subjects in the context of the new protocol endpoints. 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. In the latter case, the Company would request a meeting with the FDA to determine the appropriate next steps toward obtaining potential regulatory approval.

The Company's proposed new primary efficacy endpoints are due in part 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. Thus, the Company believes that comparing the pre-treatment baseline disease to the observed improvement in the severity of clinical symptoms at Day 14 in the enrolled Study population will provide a reasonable estimation of the efficacy of bucillamine on clinically meaningful aspects of the disease. Symptoms such as, but not limited to, fever or chills, cough, shortness of breath or difficulty breathing, heart rate, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea have clinical relevance.

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.