Revive Therapeutics Announces Submission of Amended Phase 3 COVID-19 Study Protocol to FDA

TORONTO, Sept. 14, 2022 -- 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 that it has filed an amended protocol to the U.S. Food & Drug Administration (“FDA”) 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.

Further to the review and analysis by the unblinded statistician team of the supporting Pre-Dose selection data from the Study, the Company has now submitted to the FDA a revised protocol for further discussion and agreement addressing a new primary efficacy endpoint, specifically, the time to resolution from COVID-19 via the polymerase chain reaction (“PCR”) test and secondary endpoints including evaluating time to clinical improvement, comparing frequency of hospitalization or death and disease course in patients with mild-moderate COVID-19 receiving Bucillamine therapy with those receiving placebo. These proposed endpoints address the shift in COVID-19 clinical outcomes observed over the course of the pandemic, and, therefore, may have more meaningful study endpoints for the FDA to consider for regulatory approval.

Should the FDA accept the amended protocol, the Data Safety Monitoring Board (“DSMB”) will review the completed Post-Dose selection data under the new protocol primary efficacy endpoint and may make a recommendation on continuing the Study or advise on halting the Study early due to positive efficacy showing statistical significance. In this case, the Company would proceed to seek regulatory approval by the FDA and other international health regulatory agencies.

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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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 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, 2021, which has been filed on SEDAR and is available under the

Company's profile at www.sedar.com.