Revive Therapeutics Provides Update on Phase 3 Clinical Trial for Bucillamine in COVID-19

The Company received positive comments from the FDA to determine potential new clinical endpoints to support Emergency Use Authorization

TORONTO, May 26, 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, is pleased to provide 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.

The Company has received positive comments from the FDA in regards to the Company's request to determine and agree on the Study's potential new primary efficacy endpoints, including the rate of sustained clinical resolution of symptoms of COVID-19, which addresses the shift in COVID-19 clinical outcome observed over the course of the pandemic, and, therefore, to have more meaningful study endpoints for the FDA to consider for potential Emergency Use Authorization. The FDA has agreed that the Company may unblind the pre-dose-selection data for the first 210 patients of the Study to further support the new primary endpoint. Before unblinding the pre-dose selection data for the first 210 patients, the Company will submit a Data Access Plan to the FDA in early June 2022 with the aim to unblind the pre-dose selection data and submit the amended Study protocol with the new primary efficacy endpoints to the FDA.

In addition, the Data Safety and Monitoring Board ("DSMB") are scheduled to meet thereafter to evaluate the interim clinical and safety data and may make a recommendation on continuing the Study or advise on halting the Study early due to positive efficacy based on other clinical outcomes such as the rate of sustained clinical resolution of symptoms of COVID-19. The DSMB supported the continuation of the Study in its last meeting as there were no serious adverse events or safety concerns reported.

The Company believes that with the Omicron variant, including the BA.2 variant, being the dominant strain over the Delta variant, there is an urgent unmet need to treat symptom resolutions in addition to preventing hospitalizations.

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.

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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.