Revive Therapeutics Provides Update on FDA Type C Meeting for Clinical Study of Bucillamine to Treat Long COVID

TORONTO, June 12, 2024 -- 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 and diagnostics for infectious diseases, medical countermeasures, and rare disorders, announced today an update on the Type C meeting written responses received by the Company from the U.S. Food & Drug Administration (“FDA”) for the evaluation of a proposed clinical study of Bucillamine, an oral thiol-based drug with anti-inflammatory and antiviral properties, as a potential treatment for Long COVID (the “Study”).

The FDA has recommended that the evaluation of Bucillamine for Long COVID be submitted as a new Investigational New Drug (“IND”) application and may cross-reference applicable sections from the Company’s current IND that evaluated the safety and efficacy of Bucillamine in patients with mild to moderate COVID-19 in a Phase 3 clinical trial. In addition, the FDA provided valuable feedback on the appropriate design, study population, and safety and efficacy measures for assessing a therapeutic benefit in patients with Long COVID.

“We are pleased with the FDA’s recommendations for our proposed clinical study, which provides a pathway for the clinical development of Bucillamine as a potential treatment for Long COVID,” said Michael Frank, CEO of Revive. “We aim to finalize the clinical study protocol and submit a new IND, which will cross reference our current IND to obtain FDA approval to proceed with the clinical trial for Long COVID.”

The CDC estimates that 7.5 percent of U.S. adults have Long COVID symptoms[1]. David Cutler, PhD, a professor of economics at Harvard University, estimates in a recent research disclosure that the total economic cost of Long COVID could be as much as $3.7 trillion[2].

Currently, the Company is exploring the use of Bucillamine as a potential treatment for Long COVID. The Company is advancing the clinical development of Bucillamine by leveraging the published research and data from its previous Phase 3 clinical trial and aims to complete the regulatory and clinical package that includes a proposed clinical study for Long COVID, incorporating the recommendations from the FDA from the Type C meeting.

On July 6, 2023, the Company announced the results of its Phase 3 clinical trial evaluating the safety and efficacy of oral Bucillamine in patients with mild to moderate COVID-19. Under the Phase 3 clinical trial primary endpoint, the proportion of patients meeting a composite endpoint of hospitalization or death from time of first dose through Day 28 following randomization, there were no deaths and four hospitalizations, of which three were from the placebo arm and one from the Bucillamine low dose group (300mg/day). No hospitalizations occurred in the Bucillamine large dose group (600mg/day). The Company evaluated certain endpoints, including the COVID-19 clinical symptoms data (i.e. cough, fever, heart rate, and oxygen saturation). Based on preliminary analyses, the data demonstrated that for patients with oxygen saturation <96% at baseline, Bucillamine had a 29.1% improvement over placebo in time to normal oxygen saturation (SpO2). Additional Phase 3 clinical trial data analyses may suggest Bucillamine’s potential for Long COVID.

A study titled “Thiol-based drugs decrease binding of SARS-CoV-2 spike protein to its receptor and inhibit SARS-CoV-2 cell entry” showed that thiol-based drugs, like Bucillamine, decrease the binding of SARS-CoV-2 spike protein to its receptor, decrease the entry efficiency of SARS-CoV-2 spike pseudotyped virus, and inhibit SARS-CoV-2 live virus infection. These findings uncovered a vulnerability of SARS-CoV-2 to thiol-based drugs and provided a rationale to test thiol-based drugs such as Bucillamine as novel treatments for COVID-19.

About Revive Therapeutics Ltd.

Revive Therapeutics is a life sciences company focused on the research and development of therapeutics and diagnostics for infectious diseases, medical countermeasures, and rare disorders. Revive prioritizes its drug development efforts to take advantage of several regulatory incentives awarded by the FDA, such as Emergency Use Authorization, Orphan Drug, Fast Track, and Breakthrough Therapy designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of nerve agent exposure and Long COVID. Revive is also advancing the development of Psilocybin-based therapeutics through various programs. For more information, visit www.ReviveThera.com.

For more information, please contact:

Michael Frank
Chief Executive Officer
Revive Therapeutics Ltd.
Tel: 1 888 901 0036
Email: mfrank@revivethera.com
Website: www.revivethera.com

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 "may", "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 management's discussion and analysis for the three and nine months ended March 31, 2024 ("MD&A"), dated May 28, 2024, which is available on the Company's profile at www.sedarplus.ca.

Source:

1. *"Nearly One in Five American Adults Who Have Had COVID-19 Still Have "Long COVID," CDC, June 6, 2022, https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220622.htm*

2. *"The Economic Cost of Long COVID: An Update," David M. Cutler, Harvard University, July 22, 2022, https://scholar.harvard.edu/files/cutler/files/long_covid_update_7-22.pdf*