Revive Therapeutics Announces Results of Phase 3 Clinical Study for Bucillamine in the Treatment of COVID-19

TORONTO, July 06, 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, today announced results of the Company’s Phase 3 clinical trial (the “Study”) (NCT04504734) evaluating the safety and efficacy of oral Bucillamine in patients with mild to moderate COVID-19. The Study did not achieve statistical significance on the clinical endpoints. The Study enrolled 713 patients with mild-to-moderate COVID-19.

Under the 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, 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), which was the dose suggested by the independent Data Safety Monitoring Board (“DSMB”) at the first interim analysis for the Post-dose selection phase of the Study. The one hospitalization event in the Bucillamine arm occurred in the low dose group (300mg/day), which was the dose abandoned after the first interim analysis per DSMB’s recommendation. Although the number of hospitalization events was small, it demonstrated a positive trend in the Post-dose selection phase of the Study. However, based on conditional power simulation to predict, under the trend observed in the data, the estimated chance of hitting statistical significance after Study enrollment completion and final analysis was only 5.48%. Thus, with a very low probability of the Study’s success and the shift in COVID-19 clinical outcomes observed throughout the pandemic, where many patients with COVID-19 were either asymptomatic or experienced mild to moderate illness and could be managed in the outpatient setting led the DSMB to recommend that the Study be halted as announced on May 12th, 2023.

The Company evaluated additional Study endpoints, including the COVID-19 clinical symptoms data (i.e. cough, fever, heart rate, and oxygen saturation), time to polymerase chain reaction (“PCR”) resolution, and quantitative PCR-based assessment of SARS CoV-2 viral load. There was no significant overall improvement trend between the Bucillamine and placebo arms for observed clinical symptoms and viral load data. However, 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). In addition, for time to PCR resolution, both Bucillamine and placebo arms had a median of 11 days for time to PCR negative and stay negative. However, the Bucillamine arm demonstrated a slightly shorter 75% percentile of 14 days vs. 15 days in placebo to achieve PCR negative. Additional analyses of the Study data are ongoing, which could support certain strategic decisions on pursuing the development and commercialization of Bucillamine.

Based on the Study’s data analyzed to date, the Company is committed to advancing the clinical and commercial development of Bucillamine and is pursuing the following strategic initiatives:

1. **Bucillamine 2.0:** Reformulating Bucillamine in an intravenous and inhaled version to expand on its potential therapeutic utility targeting rare disorders such as ischemia-reperfusion injury (i.e. organ transplantation), acute respiratory distress syndrome, and potential medical countermeasures (i.e. terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease), that may come with regulatory incentives awarded by the FDA, such as emergency use authorization, orphan drug, fast track, and breakthrough therapy designations.
2. **Pharmaceutical Partnerships:** Work with interested pharmaceutical partners to pursue potential domestic and international regulatory approvals and new clinical studies for infectious, inflammatory and respiratory disorders.
3. **Government Support:** Seek out potential funding opportunities offered by, but not limited to, the Biomedical Advanced Research and Development Authority (BARDA), the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

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. There can be no assurance that the Company will proceed with the clinical development and regulatory approvals of Bucillamine for COVID-19 in the U.S. and internationally.

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 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.