Revive Therapeutics Announces U.S. FDA Recommendation to Proceed Directly Into A Phase 3 Confirmatory Clinical Trial

TORONTO, April 23, 2020 -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (CSE: RVV), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, announced today that it has received positive feedback from the U.S. Food and Drug Administration (“FDA”) in response to the Company’s Pre-Investigational New Drug (“pre-IND”) meeting that was announced on April 3, 2020. The FDA recommended that the Company proceed directly into a Phase 3 confirmatory clinical trial (“Phase 3 study”) to evaluate Bucillamine for the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection in order to ensure expeditious evaluation of the safety and efficacy of Bucillamine.

“FDA’s support in advising Revive to move directly into a Phase 3 confirmatory trial provides an acknowledgment for the potential of Bucillamine in the treatment of COVID-19,” said Michael Frank, Chief Executive Officer of Revive. "Entering into a Phase 3 study is a major milestone for the Company, and we are excited to unlock the full potential of Bucillamine not only for this virus but also for other infectious diseases that we will investigate in the future.”

In addition to its recommendation, the FDA provided valuable guidance on study design and outcome measures for the Phase 3 study. Importantly, the FDA agreed that Revive could rely on its data included in its previous IND with Bucillamine for gout to support the COVID-19 Phase 3 study and, therefore, the Company did not have to perform any Phase 1 or Phase 2 clinical studies. The Company, along with its Contract Research Organization, Pharm-Olam, LLC, and its clinical development team led by Dr. Kelly McKee, Jr., MD, MPH, Chief Scientific Officer consultant and Dr. Onesmo Mpanju, PhD, Regulatory Affairs consultant, are actively incorporating the pre-IND meeting guidance and preparing the package for submission to the FDA. The Company expects to file the final IND within the next 60 days and will plan to initiate the Phase 3 study thereafter.

Scientific Rationale of Bucillamine

Preclinical and clinical studies have demonstrated that reactive oxygen species contribute to the destruction and programmed cell death of pulmonary epithelial cells.[1] N-acetyl-cysteine (NAC) has been shown to significantly attenuate clinical symptoms in respiratory viral infections in animals and humans, primarily via donation of thiols to restore antioxidant and to reduce the activity of cellular glutathione [2,3,4,5]. Bucillamine (N-(mercapto-2-methylpropionyl)-l-cysteine) has a well-known safety profile and is prescribed in the treatment of rheumatoid arthritis in Japan and South Korea for over 30 years. Bucillamine, a cysteine derivative with two thiol groups, has been shown to be 16 times more potent as a thiol donor in vivo than NAC [6]. The drug is non-toxic with high cellular permeability. The basis of the clinical study will analyze if Bucillamine has the potential, via restoration of glutathione activity and other anti-inflammatory activity, to lessen the negative consequences of SARS-CoV2 infection in the lungs and to help treat COVID-19 manifestations.

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 (or SARS-2 Coronavirus) at this time.

The Company will continue to announce its Phase 3 study initiatives as they unfold.

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 strains including COVID-19. With its recent 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 Offering, including the intended use of proceeds. 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, 2019, which has been filed on SEDAR and is available under the Company's profile at www.sedar.com.

References

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