Revive Therapeutics Announces IRB Approval of US Expanded Access Treatment Program (Compassionate Use) for Bucillamine in COVID-19

TORONTO, Sept. 16, 2020 -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (CSE: RVV, USA: RVVTF), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, is pleased to announce that the Company’s expanded access protocol (“EAP”) for compassionate use of Bucillamine in the treatment of COVID-19 received approval from the independent Institutional Review Board ("IRB"). The EAP for compassionate use is a multi-center, open label study of Bucillamine in hospitalized patients with severe COVID-19 and is being done to complement the Company’s Phase 3 COVID-19 study in the U.S. Revive expects to have patients enrolled in the United States this month.

“With the IRB approval of the expanded access protocol by Advarra, a premier IRB services company in North America, hospitalized patients with severe COVID-19 may access Bucillamine under the FDA compassionate use program under medical supervision by their physician,” said Michael Frank, Revive’s Chief Executive Officer. “The EAP serves as an option for patients that are not eligible for inclusion criteria in our Phase 3 clinical study in COVID-19 and the resulting data from the EAP will be valuable in supporting our clinical development of Bucillamine.”

The EAP for compassionate use provides physicians with access to Bucillamine under Revive’s existing Investigational New Drug (“IND”) application for COVID-19. According to the FDA, expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

About the Expanded Access Study

The expanded access study is titled, “Multi-Center, Open-Label, Expanded Access Study of Bucillamine in Hospitalized Patients with Severe COVID-19 (**EA-ARISE**)”. Patients will receive Bucillamine 200 mg orally, 3 times a day (TID), for up to 14 days. The objective is to monitor the safety and efficacy of Bucillamine (600 mg/day) and any clinical symptoms when administered up to 14 days in hospitalized patients with severe COVID-19. Following completion of the treatment course, follow up safety assessments will be performed by a study nurse 14 and 42 days following the end of treatment.

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.

Scientific Rationale of Bucillamine for COVID-19

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 increase antioxidant activity of cellular glutathione2,3,4,5. 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 increasing glutathione activity and other anti-inflammatory activity, to lessen the destructive consequences of SARS-CoV-2 infection in the lungs and attenuate the clinical course of COVID-19.

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 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

1. S Ye et al, Inhibition of Reactive Oxygen Species Production Ameliorates Inflammation Induced by Influenza A Viruses via Upregulation of SOCS1 and SOCS3., American Society for Microbiology. 2015 Mar;89(5):2672-2683).

2. L. Carati et al, Attenuation of influenza-like symptomatology and improvement of cell-mediated immunity with long-term N-acetylcysteine treatment., ***Eur Respir J.*** *1997 Jul;10(7):1535-41).*

3. M Mata et al, N-acetyl-L-cysteine (NAC) inhibit mucin synthesis and pro-inflammatory mediators in alveolar type II epithelial cells infected with influenza virus A and B and with respiratory syncytial virus (RSV)., Biochem Pharmacol. 2011 Sep;82 (5):548-55.

4. D Ungheri et al, Protective effect of n-acetylcysteine in a model of influenza infection in mice., Int J Immunopathol Pharmacol. 2000 Sep-Dec;13(3):123-128.

5. RH Zhang et al, N-acetyl-l-cystine (NAC) protects against H9N2 swine influenza virus-induced acute lung injury., Int Immunopharmacol. 2014 Sep;22(1):1-8).

6. LD Horwitz, Bucillamine: a potent thiol donor with multiple clinical applications, ***Cardiovasc Drug Rev.*** *2003 Summer;21 (2):77-90).*