Revive Therapeutics Announces Filing of FDA Pre-IND Meeting

TORONTO, April 03, 2020 -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (CSE: RVV), a life sciences company focused on the research and development of therapeutics for infectious diseases and rare disorders, announced today that it has filed its Pre-Investigational New Drug (“pre-IND”) meeting request with the U.S. Food and Drug Administration (“FDA”) for Bucillamine in the treatment of the coronavirus disease (“COVID-19”). The Company will rely on its previous FDA IND submissions of Bucillamine to expedite communications and obtain FDA acceptance to proceed to a phase 2 clinical study. The Company has previously been granted Phase 2 study approval for the treatment of Gout and Cystinuria with Bucillamine.

Revive, along with the assistance of Pharm-Olam, LLC. is finalizing the clinical study protocol to advance to a Phase 2 clinical trial in the U.S. The proposed Phase 2 clinical study contemplates a multi-center, randomized, double-blind, placebo-controlled, clinical study of Bucillamine in patients with mild to moderate symptoms. The proposed objectives of the study are to evaluate disease course in patients receiving Bucillamine therapy compared to a placebo, the safety of Bucillamine therapy when administered up to 14 days, and the time to clinical improvement in patients with symptoms receiving Bucillamine compared with a placebo.

“We are excited to expedite the clinical investigation of Bucillamine in a proposed phase 2 clinical study in the U.S., and we believe our history with the FDA for Bucillamine will provide a compelling case”, said Michael Frank, Revive’s Chief Executive Officer. “We will also seek to expand the clinical investigation of Bucillamine in Asian regions, with a particular interest in Japan and South Korea where Bucillamine has been prescribed for treating arthritis for over 30 years. We are in discussion with various contract research organizations (‘CRO’) in these regions.”

Innovative therapies to treat and modify the natural course of the disease are urgently needed. 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 influenza and SARS CoV2 infection in the lungs and to help treat these conditions.

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 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 was previously 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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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.

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