Revive Therapeutics Provides Corporate Update on its COVID-19 and Infectious Diseases Programs

TORONTO, March 30, 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, is pleased to provide a corporate update on its plans for the Company’s coronavirus disease (“COVID-19”) and infectious diseases programs. The Company seeks to advance its product pipeline to human clinical studies in regions where its products have regulatory approval to investigate in clinical studies and are approved for sale, such as the U.S. and in Asia-Pacific Countries (“APAC”).

“We have strengthened our scientific and clinical team that will allow us to pursue the clinical development of Bucillamine in the potential treatment of not only COVID-19 but also other infectious diseases and we are seeking to advance Bucillamine for COVID-19 towards a potential U.S. FDA Phase 2 clinical study and a clinical study in one of the APAC countries,” said Michael Frank, Revive’s Chief Executive Officer. “Revive has built a robust product pipeline that has a particular focus on infectious diseases and rare disorders and is discovering and developing new therapeutic uses of drugs such as Bucillamine, Psilocybin and Cannabidiol. We are steadily advancing our product development programs that will unlock the potential value of Revive and we are continuing to expand our product pipeline in infectious diseases and rare disorders.”

The Company is currently focused on advancing the clinical development for Bucillamine, which has a proven safety profile and has been prescribed for arthritis in Japan and South Korea for over 30 years and is being repurposed by the Company as a potential treatment of infectious diseases, including COVID-19. Revive has applied for a provisional patent with the U.S. Patent and Trademark Office entitled “Use of Bucillamine in the Treatment of Infectious Diseases” (Serial No. 62/991,996) and the Company is targeting COVID-19 as its lead indication. In the past, the Company has explored the use of Bucillamine in the treatment of acute gout flares in a Phase 2 study in the U.S. under its Investigational New Drug (“IND”) application that was granted and accepted by the U.S. Food and Drug Administration (“FDA”). Additionally, the Company has explored the use of Bucillamine in the treatment of cystinuria where it has received FDA orphan drug status and its IND was also accepted by the FDA to conduct a Phase 2 study in the U.S.

The Company is leveraging its U.S. FDA regulatory and clinical experience with Bucillamine to further its clinical initiatives with Bucillamine for the potential treatment of COVID-19 and other infectious diseases. Revive has taken the necessary steps to unlock the full potential of Bucillamine for infectious diseases, including COVID-19, by strengthening its scientific and clinical development team to realize the potential commercial value of the Company’s product pipeline. The Company recently announced it has engaged Dr. David Boulware, MD, MPH, an internationally recognized infectious disease expert and Professor of Medicine, Division of Infectious Diseases and International Medicine at The University of Minnesota, who is currently the Principal Investigator of a globally recognized COVID-19 clinical trial (ClinicalTrials.gov Identifier: **NCT04308668**). The Company has also retained Pharm-Olam, LLC, with proven clinical experience in infectious diseases completing over 100 clinical studies in approximately 19,000 patients at over 2,000 clinical sites, to serve as the Company’s Contract Research Organization (“CRO”) to advance the future clinical study for Bucillamine in the treatment of COVID-19 and potentially other infectious diseases. In addition, Revive has added Dr. Kelly McKee, Jr., MD, MPH as Chief Scientific Officer consultant, bringing over 30 years of experience in research and development expertise in vaccines, emerging diseases, biodefense, respiratory viral infections, and Dr. Onesmo Mpanju, PhD as Regulatory Affairs consultant, having nearly 30 years of drug regulatory experience and a past reviewer at the U.S. FDA, Center for Biologics Evaluation & Research and a key consultant to the Bill & Melinda Gates Foundation.

The Company is finalizing its regulatory package and clinical study plan for Bucillamine in the treatment of COVID-19 and it will submit for regulatory approval, by way of an IND application submission to the U.S. FDA, to investigate Bucillamine in a proposed Phase 2 clinical study. Revive will also seek to expand the clinical investigation of Bucillamine for COVID-19 in APAC regions, with a particular interest in Japan and South Korea.

Scientific Rationale for the Investigation of Bucillamine to Treat Infectious Diseases including COVID-19

Current antiviral interventions for influenza have exhibited modest efficacy, especially in improving mortality in at-risk populations, such as the elderly.[1,2] Novel antivirals have been plagued by poor oral bioavailability and lack of efficacy when not delivered early.1 This is because these drugs mostly act to prevent the early processes of virus binding to cells or viral replication.[2] Thiols, particularly N-acetylcysteine (NAC), with antioxidant and reducing activity have been investigated as effective therapies that abrogate the potential for influenza to cause severe disease.[3,4,5] Restoration of glutathione, the major intracellular thiol antioxidant, is a critical functional activity of NAC.[6] Reactive oxygen species (ROS) generation during influenza virus infection aggravate destructive inflammation and programmed death of epithelial cells.[7] Studies in human cells and animal models have shown that NAC works to prevent acute lung injury caused by influenza virus infection through inhibition of these ROS-mediated mechanisms.[4,7] NAC has been investigated clinically and found to significantly attenuate clinical symptoms associated with influenza infection, especially in elderly at-risk patients.[5] While NAC is easily taken up by cells and has low toxicity, clinical efficacy has required long-term and high-dose administration because of modest relative potency, limiting its clinical applicability.

Bucillamine (N-(mercapto-2-methylpropionyl)-l-cysteine), which has a well-known safety profile and is prescribed in the treatment of rheumatoid arthritis in Japan and South Korea for over 30 years, is a cysteine derivative with 2 thiol groups that is

16-fold more potent than NAC as a thiol donor in vivo, giving it vastly superior function in restoring glutathione and therefore greater potential to prevent acute lung injury during influenza infection.[8] Bucillamine has also been shown to prevent oxidative and reperfusion injury in heart and liver tissues[8] and is highly cell permeable for efficient delivery into cells.[8,9] Bucillamine has unrealized potential for the treatment of influenza with both proven safety and proven mechanism of action similar to that of NAC, but with much higher potency, mitigating the previous obstacles to using thiols therapeutically. It is also reasonable to hypothesize that similar processes related to ROS are involved in acute lung injury during nCov-19 infection, possibly justifying the investigation of bucillamine as an intervention for 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 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 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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