Revive Therapeutics Files for FDA Orphan Drug Designation for Bucillamine in the Prevention of Ischemia-Reperfusion Injury During Liver Transplantation

TORONTO, Nov. 23, 2021 (GLOBE NEWSWIRE) -- 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, is pleased to announce it has filed an application with the U.S. Food and Drug Administration ("FDA") to receive Orphan Drug Designation ("ODD") for Bucillamine for the prevention of ischemia–reperfusion injury (IRI) during liver transplantation.

Currently, there is no approved treatments available for IRI. Liver ischemia-reperfusion injury is a major complication of liver transplantation and is one of the leading causes for post-surgery hepatic dysfunction leading to an increased risk of post-operative morbidity and mortality. According to the United Network for Organ Sharing (“UNOS”) there were 8,906 liver transplants in 2020 and at the time of the ODD submission there were 11,664 on the waiting list for a liver transplant. Although many therapeutic strategies have been shown to be effective in controlled experimental models, most have yielded equivocal results in clinical practice or have yet to reach human clinical trials.

Revive believes the use of Bucillamine during liver transplantation has the potential to be a safe and effective approach to address the unmet medical need for a novel strategy to limit or prevent IRI. Bucillamine, a cysteine derivative that contains two donatable thiol groups, in the context of IRI is capable of replenishing the thiol group in glutathione, thereby reactivating this endogenous defense against oxidant injury. In addition, Bucillamine appears to have anti-inflammatory effects unrelated to its antioxidant effect. Bucillamine has the potential to address the shortage of quality organs by reducing the susceptibility to IRI of steatotic livers thereby making these livers available for transplants. Bucillamine also has the potential to improve graft function and patient outcome by preventing or lessening IRI.

Michael Frank, CEO of Revive commented: “We are continuing to advance novel uses of Bucillamine not only as a treatment for infectious diseases, but also for rare conditions that have no treatment options such as IRI. The FDA orphan drug application for Bucillamine as a potential solution in preventing IRI during liver transplantation and subsequently to other organ transplants complements our overall strategy of developing Bucillamine as a strong platform for other conditions.”

The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). The FDA grants ODD status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. ODD would qualify bucillamine for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain clinical drug testing costs, activities, eligibility for orphan drug grants, and the waiver of the FDA New Drug Application filing fee of approximately USD $2,400,000.

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 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, 2021, which has been filed on SEDAR and is available under the Company’s profile at www.sedar.com.