Revive Therapeutics Provides Update on the Psilocybin Clinical Study for Methamphetamine Use Disorder and Oral Psilocybin Thin Film Strip Program

TORONTO, Sept. 16, 2022 -- 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 provide an update on the Company's Phase I/II clinical study of oral psilocybin in the treatment of methamphetamine use disorder and the development of its proprietary oral psilocybin thin film strip product.

"We continue to focus on building a specialty psilocybin-based product pipeline to treat mental illness, substance abuse and neurological disorders. We intend to advance the development of our oral psilocybin thin film strip product for these indications. In parallel, we are working on our first clinical study evaluating oral psilocybin in the treatment of methamphetamine use disorder to validate its use in substance abuse indications. The clinical data from this study will be used to support late-stage clinical trials with our oral psilocybin thin film strip product," said Derrick Welsh, COO of Psilocin Pharma, a division of Revive.

Oral Psilocybin for Methamphetamine Use Disorder

The Company is currently evaluating the use of oral psilocybin as a potential treatment for methamphetamine use disorder with the University of Wisconsin-Madison. Under an investigator-initiated IND, led by Dr.'s Christopher Nicholas and Paul Hutson, the Phase I/II clinical study (the "Study") to evaluate the safety and feasibility of psilocybin in adults with methamphetamine use disorder received both FDA and Institutional Review Board approval. The Study is being conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy.

The clinical data that is generated from the Study will provide proprietary and valuable information on the safety, efficacy and dosing of oral psilocybin to support future pivotal FDA clinical studies for the Company's proposed oral psilocybin thin film strip product. In addition, the Company will have exclusive access to key intellectual property from this study to support development, regulatory and commercial initiatives.

Oral Psilocybin Thin Film Strip Product

The Company has initiated the product development program under a feasibility agreement with LTS Lohmann Therapie-Systeme AG, a leader in pharmaceutical oral thin films, to develop and manufacture a proprietary oral psilocybin thin film strip product for mental illness, substance abuse and neurological disorders. Prototypes of the oral psilocybin thin film strip product have been developed and are being optimized for use in upcoming IND-enabling studies. The Company expects to conduct a first-in-human clinical study in 2023.

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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and timing of such future events. Forward looking information in this press release includes information with respect to the 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.