Revive Therapeutics Provides Update on Psychedelics Clinical Product Pipeline

- *Focusing on novel uses, production and delivery forms of psilocybin as a next generation solution for mental illness, substance abuse and neurological disorders*
- *Advancing to FDA clinical studies for methamphetamine use disorder and stroke*

TORONTO, Aug. 10, 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 provide an update on the Company’s psychedelics development and clinical programs with a focus on psilocybin.

Michael Frank, CEO of the Company, commented, "We are advancing a robust psychedelics-based product pipeline that includes product development, preclinical and clinical studies that aim to unlock the potential therapeutic value of psilocybin in various uses, formulations and delivery methods to treat mental health, substance abuse and neurological disorders. Revive is embarking on the next stage of growth of its psychedelics strategy by focusing on building key partnerships with US academic institutions and other leading organizations, as well as developing intellectual property and entering into FDA clinical studies with psilocybin.”

Psilocybin in the Treatment of Methamphetamine Use Disorder

The Company is working with the Board of Regents of the University of Wisconsin System under a clinical trial agreement to conduct a Phase I/II clinical study to evaluate the safety and feasibility of psilocybin in adults with methamphetamine use disorder. Study start-up activities have taken place and enrollment activities are to continue throughout the remainder of the year. As a result of the study, clinical data will provide proprietary and valuable information on the safety, efficacy and dosing of psilocybin to support future pivotal FDA clinical studies in oral forms of delivery including oral thin film strips. The clinical study will be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy, which holds a Wisconsin special authorization and DEA license to perform clinical research with psilocybin. In addition, the Company will have exclusive access to key intellectual property from this study to support development, regulatory and commercial initiatives.

Psilocybin in the Treatment of Traumatic Brain Injury (TBI) and Stroke

The Company is advancing the research and intellectual property acquired from PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) on psilocybin as a potential solution to managing TBI and stroke. Preclinical studies demonstrated that psilocybin, given after injury, improved cognitive function in TBI mice. The Company is proceeding to an FDA clinical study to be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy. Start-up activities have already begun and patient enrollment is expected to commence in Q4-2021.

Psilocybin Oral Thin Film Strip Development

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 psilocybin oral thin film strip for mental illness, substance abuse and neurological disorders. Research grade prototypes will be available to evaluate dosing and delivery rates in various dosage forms with the expectation to conduct clinical studies in 2022.

Psilocybin Biosynthesis Program

Under its research collaboration with North Carolina State University (NC State), the Company is developing a novel biosynthetic version of psilocybin based on a natural biosynthesis enzymatic platform developed by Dr. Gavin Williams, Professor and Researcher at NC State. The biosynthetic platform developed by Dr. Gavin Williams provides a potentially simple and efficient method for rapidly producing natural products, such as psilocybin, using an engineered enzymatic pathway in E. coli. Certain technical milestones have been achieved to date, offering a clear path towards completing validation methods to demonstrate a novel yet simple production process of biosynthetic psilocybin that can be used at a critical scale for clinical and commercial use.

Psilocybin International Research and Commercialization

The Company recently entered into an agreement with the University of Health Sciences Antigua to utilize Revive’s novel psychedelic-assisted therapies including its tannin-chitosan delivery system and to pioneer the clinical research and development of psychedelics in Antigua and Barbuda. Clinical research will be conducted at the University in Q4-2021 with the aim for commercialization in 2022 in Antigua and Barbuda. Once approved for sale, the Company will seek commercial partnerships with specialty pharmaceutical companies in the Caribbean and Latin America.

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. Through its subsidiary 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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