Revive Therapeutics Provides Update of Psilocybin Pharmaceutical Programs

IRB approval to initiate Phase 2 study for methamphetamine abuse disorders

Advancing psilocybin oral thin film, microneedle patch and biosynthesis programs

TORONTO, Jan. 17, 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 psilocybin pharmaceutical development programs.

“Revive is building a specialty psilocybin-based product pipeline to treat mental illness, substance abuse and neurological disorders. We are embarking on our first clinical study evaluating psilocybin in the treatment of methamphetamine use disorder and advancing the development of an oral psilocybin thin file strip and psilocybin microneedle patch, which will offer flexible therapeutic solutions of psilocybin for unmet medical needs.”

Psilocybin for Methamphetamine Use Disorder

The Company is evaluating psilocybin as a potential treatment for methamphetamine use disorder with the University of Wisconsin-Madison through a clinical trial agreement. Under an investigator-initiated IND, led by Dr.'s Christopher Nicholas and Paul Hutson, the Phase I/II clinical study to evaluate the safety and feasibility of psilocybin in adults with methamphetamine use disorder received Institutional Review Board (“IRB”) approval. 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 the Company’s proposed oral psilocybin thin film strip. The clinical study will be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy. In addition, the Company will have exclusive access to key intellectual property from this study to support development, regulatory and commercial initiatives.

Psilocybin for Stroke

The Company is evaluating psilocybin as a potential treatment for stroke with the University of Wisconsin-Madison. Under the same investigator-initiated IND, led by Dr.'s Christopher Nicholas and Paul Hutson, the proposed Phase I/II clinical study protocol to evaluate the safety and feasibility of psilocybin for stroke is expected to be submitted to the IRB in February. 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 the Company’s proposed oral psilocybin thin film strip. The clinical study will be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy. In addition, the Company will have exclusive access to key intellectual property from this study to support development, regulatory and commercial initiatives.

Psilocybin Oral Thin Film Strip

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 prototype development is underway to support IND-enabling studies with the expectation to conduct a clinical study in Q4-2022.

Psilocybin Microneedle Patch

The Company entered into a research collaboration agreement with PharmaTher Holdings Ltd. (“PharmaTher”) (OTCQB: PHRRF) (CSE: PHRM) to evaluate the delivery of psilocybin with PharmaTher’s proprietary microneedle patch technology for neuropsychiatric disorders. The project plan has been finalized and the Company will initiate IND-enabling studies with the expectation to conduct a clinical study in Q4-2022.

Psilocybin Biosynthesis

The Company is developing a novel biosynthetic version of psilocybin based on a natural biosynthesis enzymatic platform under its research collaboration with North Carolina State University developed by Dr. Gavin Williams, Professor and Researcher at NC State. The biosynthetic platform 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. The Company expects to complete a research-grade batch of psilocybin for research in Q2-2022 with the aim to conduct clinical studies in 2023.

Psilocybin International Research

The Company 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 is expected to begin shortly 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.

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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