Revive Therapeutics Provides Update on its Clinical Development Plan For Rare Liver Diseases

TORONTO, January 6, 2020 (GlobeNewswire) -- Revive Therapeutics Ltd. (“Revive” and the “Company”) (CSE: RVV), a cannabis life sciences company focused on novel cannabinoid-based treatments for rare inflammatory diseases, is pleased to provide an update on the Company’s clinical development plan for Autoimmune liver diseases, which includes Cannabidiol in the treatment of Autoimmune Hepatitis.

“Revive is leveraging its unique intellectual property portfolio and is focusing its efforts on building a pipeline of cannabinoid-based treatments for rare inflammatory diseases targeting multi-billion dollar markets,” said Michael Frank, Chief Executive Officer of Revive. “Our initial focus is advancing the clinical development of Cannabidiol in the treatment of Autoimmune Hepatitis towards a first-in-kind human clinical trial under a U.S. Investigational New Drug that will pave the way for pursuing our objectives in expanding our product pipeline of novel cannabinoid-based treatments for rare Autoimmune liver diseases and in bringing novel, targeted cannabinoid therapies to patients that need them most.”

Revive aims to build a portfolio of cannabinoid-based drugs for the treatment of rare inflammatory diseases with its initial focus on Autoimmune liver diseases (AILD). AILD are relatively rare diseases that are comprised of namely four indications including Autoimmune hepatitis (AIH), primary biliary cirrhosis, primary sclerosing cholangitis, and immunoglobulin G4 related cholangitis. These are chronic diseases that result in significant morbidity and mortality.

Revive will focus on the clinical development of Cannabidiol (CBD) in the treatment of AIH with plans to submit an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in 1H 2020 for a proposed Phase 1/2a clinical study to determine the recommended dose of CBD for future clinical studies, to assess its safety, efficacy and clinical benefit, as well as to support a New Drug Application (“NDA”). The

Company aims to have a pre-IND meeting with the FDA to obtain feedback of Revive's intended clinical development plan, including a proposed Phase 1/2a study design.

Revive's program is to meet a clear unmet medical need in patients with AIH. AIH is a rare inflammatory condition of the liver that can affect all ages and gender across the world. If not treated properly, may cause liver fibrosis or cirrhosis, liver failure requiring a liver transplant, and even death. The prevalence of AIH is estimated at 75,000 patients in the U.S. The current standard of care for AIH is the use of steroids alone or steroids combined with azathioprine. It has been noted in medical literature that the current standard of care when used in a certain period of time has caused severe treatment-related side effects in 13%, treatment failure in 9%, incomplete response in 13%, and relapse after drug withdrawal up to 86% of patients with AIH (Source: World J Gastroenterol. 2010 Feb 28; 16(8): 934–947). Therefore, given the unwanted outcomes associated with a steroid-based therapy, an alternative steroid-free treatment option such as CBD, with its known safety profile, may provide a potential solution for an improved treatment strategy for those patients unresponsive to, intolerant of, or non-adherent with a steroid-based therapy for AIH.

Revive has an exclusive license from South Carolina Research Foundation for its intellectual property for the use of CBD, either in synthetic or natural form, in the treatment of autoimmune hepatitis (U.S. patent No. 8242178). Also, the FDA has granted to Revive orphan drug designation for CBD in the treatment of AIH, which provides valuable incentives that could accelerate the approval process, including seven-year market exclusivity, tax credits on U.S. clinical trials, fast-tracking of regulatory proceedings, and exemption from certain fees, such as waiver of filing fees under the Prescription Drug User Fee Act (PDUFA), and orphan drug grants.

Additionally, the Company will now not be proceeding with the subscription receipt private placement offering announced on November 12, 2019.

ABOUT REVIVE THERAPEUTICS LTD.

Revive Therapeutics Ltd. is a cannabis life sciences company focused on the research, development and commercialization of novel cannabinoid-based products. The Company's novel cannabinoid delivery technology is being advanced to fill the medical needs for diseases and disorders such as pain, inflammation, and wound care. Revive's cannabinoid pharmaceutical portfolio focuses on rare inflammatory and liver diseases. For more information, visit **www.ReviveThera.com**.

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*Certain statements contained in this press release constitute forward-looking information. 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. Actual future results may differ materially. 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. Because of the risks, uncertainties and assumptions contained herein, investors should not place undue reliance on forward looking-information. The foregoing statements expressly qualify any forward-looking information contained herein. Factors that may cause actual results to differ materially from those anticipated by these forward looking statements include: uncertainties associated with the merger; uncertainties associated with reaching a definitive agreement to merge; uncertainties associated with obtaining regulatory approvals; the need to establish additional corporate collaborations, distribution or licensing arrangements; the Company's ability to raise additional capital if and when necessary; intellectual property disputes; increased competition from pharmaceutical and cannabis-centered companies; changes in equity markets, inflation, and changes in exchange rates; and other factors as described in detail in the Company's Management's Discussion & Analysis for the year ended June 30, 2019, the Company's Annual Information Form for the year ended June 30, 2018, and continuous disclosure filings, all of which may be viewed on SEDAR (**www.sedar.com**). Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements and information, which are qualified in their entirety by this cautionary statement. Except*

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