Revive Provides Update on its Clinical Development Plan for Cannabidiol in the Treatment of Autoimmune Hepatitis

TORONTO, Feb. 18, 2020 -- Revive Therapeutics Ltd. ("Revive" or the "Company"), a company focused on the research, development and commercialization of novel cannabinoid-based and life sciences products, is pleased to provide an update on the Company's clinical development plan for Cannabidiol ("CBD") in the treatment of Autoimmune Hepatitis (AIH).

Revive is currently in the process of preparing its Investigational New Drug ("IND") application for submission to the U.S. Food and Drug Administration ("FDA") for CBD in the treatment of AIH. The Company plans to submit the IND within ninety days with the objective to proceed with a proposed Phase 1/2a clinical study to determine the recommended dose of CBD for future clinical studies of AIH, to assess its safety, efficacy and clinical benefit, as well as to support a New Drug Application ("NDA") for FDA approval. The Company aims to initiate a clinical study by the end of Q2 or early Q3-2020.

"Revive is focused on advancing its cannabinoid-based product pipeline towards human clinical studies with our lead program being CBD in the treatment of AIH, a rare liver disease that represents a large market opportunity globally," said Michael Frank, Chief Executive Officer of Revive. "Our objective in proceeding with a first-in-kind human clinical trial under a U.S. IND will further support our cannabinoid pharmaceutical initiatives by expanding into other rare diseases that Revive is pursuing such as the use of CBD in the prevention of ischemia and reperfusion injury ("IRI") resulting from solid organ transplantation, which includes liver, kidney, heart and lung. The Company has received FDA orphan drug designation for CBD in both AIH and IRI."

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.

About Revive Therapeutics Ltd.

Revive is a company focused on the research, development and commercialization of novel cannabinoid-based and life sciences products. Revive's 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 areas such as liver disease. The company has been granted FDA orphan drug status designation for the use of CBD to treat auto-immune hepatitis (liver disease) and FDA orphan drug status designation for the use of CBD to treat ischemia and reperfusion injury from organ transplantation.

For more information, visit www.ReviveThera.com.

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Cautionary Statement

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 IND submission to the FDA, including plans to submit the IND within sixty to ninety days, a proposed Phase 1/2a clinical study, and the aim to initiate a clinical study by the end of Q2-2020. 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. Factors that may cause actual results to differ materially from those anticipated by these forward looking statements include: the risk that the Company may not be able to submit the IND to the FDA; the Company many not obtain approval to proceed with a human clinical study; the inability of the Company to satisfy all conditions to proceed with a human clinical study and the risk of unforeseen delays in the submission of the IND. Reference is also 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, 2019, which has been filed on SEDAR and is available under the Company’s profile at www.sedar.com.