Revive Therapeutics Applies To FDA For Orphan Drug Designation of Cannabidiol For Treatment Of Liver Transplantation

TORONTO, Aug. 22, 2018 -- **Revive Therapeutics Ltd.** (TSX VENTURE:RVV) (OTCQB:RVVTF) (FSE:31R) **("Revive" or the "Company")**, a specialty medical cannabis company, today announced that it has submitted an application to the U.S. Food and Drug Administration ("FDA") seeking orphan drug designation of cannabidiol ("CBD") for the treatment of hepatic ischemia and reperfusion injury ("IRI") during liver transplantation.

"This orphan drug designation application builds on our pharmaceutical strategy of creating a unique portfolio of cannabinoid therapies targeting rare inflammatory and liver diseases and disorders, and supports our business development activities in partnering with medical-focused licensed producers of cannabis and pharmaceutical companies," said Fabio Chianelli, President of Revive. "We are dedicated to commercializing novel medical cannabis-based products and therapies as part of our overall ambition in becoming a leading global specialty medical cannabis company, and we are excited in the long-term potential of plant-derived cannabinoid prescription medicines for rare diseases and disorders, which we believe has been validated by the FDA approval of the GW Pharmaceuticals plc EPIDIOLEX®. Revive recently announced that the FDA granted orphan drug designation for cannabidiol in the treatment of autoimmune hepatitis, a rare liver disease, and our orphan drug application in liver transplantation is complementary to our liver disease pharmaceutical strategy."

Liver ischemia-reperfusion injury is a major complication of liver transplantation and is one of the leading causes for post-surgery hepatic dysfunction leading to an increased risk of postoperative morbidity and mortality. According to the United Network for Organ Sharing ("UNOS") there have been 160,722 liver transplants performed between January 1, 1988 and July 30, 2018. Currently there are 13,773 individuals on the waiting list for a liver transplant. Quickly restoring blood supply of ischemic liver as soon as possible is crucial for avoiding or reducing injury from ischemia, whereas strategies used to attenuate the damage induced by reperfusion, including ischemic preconditioning, ischemic postconditioning, and machine perfusion. These strategies are expensive, sometimes hard to perform in clinical surgeries, and difficult in maintaining liver functions in the case of acute injuries. Revive believes that the immunosuppressant and anti-inflammatory protective effects of CBD may provide a novel, more beneficial strategy to attenuate the damage induced by ischemia and reperfusion during liver transplantation.

Under the Orphan Drug Act of 1983, the FDA provides incentives for companies developing treatments that are expected to provide significant therapeutic advantage over existing treatments, and that target rare medical conditions affecting fewer than 200,000 U.S. patients per year. Incentives include 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 Liver Disease
Liver disease is described as irregular functioning of liver, causing disorders like hepatitis, fatty liver (NASH), and cirrhosis. There are over 100 described diseases of the liver affecting at least 30 million people alone in the U.S. A number of factors are driving the liver disease treatment market, which includes rapidly changing lifestyle patterns such as increasing alcohol consumption, unhealthy diets, and increasing prevalence of liver diseases. Liver diseases can result from injury to the liver caused by hepatitis C virus (HCV), hepatitis B virus (HBV), obesity, chronic excessive alcohol use or autoimmune diseases. Major drug categories used in the treatment of liver diseases includes anti-rejection drugs, vaccines, immunosuppressant, chemotherapy drugs and antiviral drugs. According to Allied Market Research titled, "World Liver Disease Treatment Market – Opportunities and Forecast, 2014 - 2022", the global market for liver disease treatment is projected to reach approximately $19.5 billion by 2022.

About Revive Therapeutics Ltd.
Revive Therapeutics Ltd. (TSX VENTURE:RVV) (OTCQB:RVVTF) (FSE:31R) is a specialty medical cannabis company focused on the research, development and commercialization of novel cannabinoid-based therapies. Additional information on Revive is available at www.ReviveThera.com.

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Revive Therapeutics Ltd. Cautionary Note Regarding Forward-Looking Statements

Neither the TSX-V nor its Regulation Services Provider (as that term is defined in the policies of the TSX-V) accepts responsibility for the adequacy or accuracy of this release.

This news release includes certain information and statements about management's view of future events, expectations, plans

and prospects that constitute "forward-looking information" that involves known and unknown risks and uncertainties, which are not comprised of historical facts, and most of which are beyond the control of Revive. Forward-looking statements include estimates and statements that describe Revive's future plans, objectives or goals, including words to the effect that Revive or its management expects a stated condition or result to occur. Forward-looking statements may be identified by such terms as "believes", "anticipates", "intends", "expects", "estimates", "may", "could", "would", "will", or "plan", and similar expressions. Specifically, forward-looking statements in this news release include, without limitation, statements regarding: Revive's orphan drug designation of cannabidiol in the treatment of hepatic ischemia and reperfusion injury ("IRI") during liver transplantation; Revive's orphan drug designation of cannabidiol in the treatment of autoimmune hepatitis; Revive's cannabis pharmaceutical, research and development, and commercialization strategy; pharmaceutical strategy of creating a unique portfolio of cannabinoid therapies targeting rare inflammatory and liver diseases and disorders; Revive's drug research and development, and commercialization plans; Revive's research, development and commercialization plans for plant-based therapies, including cannabinoids; Revive's cannabinoid delivery technology; Revive's cannabinoid-based product pipeline; the timing of operations; and estimates of market sizes and conditions. These statements involve known and unknown risks, uncertainties, and other factors that may cause actual results or events, performance, or achievements of Revive to differ materially from those anticipated or implied in such forward-looking statements. Since forward-looking statements are based on assumptions and address future events and conditions, by their very nature they involve inherent risks and uncertainties. Revive believes that the expectations reflected in these forward-looking statements are reasonable, but there can be no assurance that actual results will meet management's expectations. In formulating the forward-looking statements contained herein, management has assumed: that business and economic conditions affecting Revive will continue substantially in the ordinary course and will be favourable to Revive; that clinical testing results will justify commercialization of the Revive's drug candidates; that Revive will be able to obtain all requisite regulatory approvals to commercialize its drug candidates; that such approvals will be received on a timely basis; and, that Revive will be able to find suitable partners for development and commercialization of its drug repurposing candidates on favourable terms. Although these assumptions were considered reasonable by management at the time of preparation, they may prove to be incorrect and no assurance can be given that such events will occur in the disclosed time frames or at all.

Factors that may cause actual results to differ materially from those anticipated by these forward-looking statements include: uncertainties associated with obtaining regulatory approval to perform clinical trials and market products; the need to establish additional corporate collaborations, distribution or licensing arrangements; Revive's ability to raise additional capital if and when necessary; intellectual property disputes; increased competition from pharmaceutical and biotechnology companies; changes in equity markets, inflation, and changes in exchange rates; and other factors as described in detail in Revive's Management's Discussion & Analysis for the period ended June 30, 2017 and Revive's other public 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 as required by law, Revive disclaims any intention and assumes no obligation to update or revise any forward-looking statements to reflect actual results, whether as a result of new information, future events, changes in assumptions, changes in factors affecting such forward-looking statements or otherwise.