

## Revive Therapeutics Announces FDA Grants Orphan Drug Designation for Cannabidiol in the Prevention of Ischemia and Reperfusion Injury from Organ Transplantation

TORONTO, Nov. 07, 2018 -- Revive Therapeutics Ltd. (TSX VENTURE: RVV) (OTCQB: RVVTF) (FSE:31R) ("Revive" or the "Company"), a specialty cannabis company focused on the research, development and commercialization of novel cannabinoid-based products, today announced that the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation for cannabidiol ("CBD") in the prevention of ischemia and reperfusion injury ("IRI") resulting from solid organ transplantation.

"We are very pleased to receive orphan drug designation for CBD in the prevention of IRI resulting from solid organ transplantation, such as liver, kidney, heart and lung, as it complements on our first FDA granted orphan drug designation for cannabidiol in the treatment of autoimmune hepatitis, a rare liver disease, and provides us with a unique cannabinoid pharmaceutical product pipeline that is in line with our overall ambition in becoming a leading global specialty medical cannabis company," said Fabio Chianelli, President of Revive. "This milestone builds on Revive's pharmaceutical strategy in developing novel cannabinoid therapies targeting both broad and rare inflammatory diseases and it supports our near-term product and business development strategy in commercializing novel cannabis-based therapies and potential partnering opportunities with licensed producers of cannabis and pharmaceutical companies."

According to the U.S. Organ Procurement and Transplantation Network, there are approximately 115,000 patients waiting for solid organ transplants in the United States, with the four most common organs transplanted being liver, kidney, heart and lung. IRI in organ transplantation can result in a higher incidence of acute and chronic rejection, as well as long-term morbidity and mortality. Quickly restoring blood supply of ischemic organs 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 organ functions in the case of acute injuries. With the shortage of organs and expensive medical strategies, it is clear that therapies need to be researched to optimize the quality of the organs that are available and to attenuate injury to transplanted organs. 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 solid organ 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 Revive Therapeutics Ltd.

Revive Therapeutics Ltd. (TSX VENTURE: RVV) (OTCQB: RVVTF) (FSE: 31R) is a specialty cannabis company focused on the research, development and commercialization of novel cannabinoid-based products. Revive is commercializing patentprotected, best-in-class cannabis-based products with first mover advantage in the multi-billion cannabis and wellness market. The Company's first product is a proprietary hemp-based cannabidiol ("CBD") chewing gum, RELICANN™, for the health and wellness and medical cannabis market offering a better alternative over conventional products. The Company's novel cannabinoid delivery technology is being advanced to fill the unmet medical needs for diseases and disorders such as pain, inflammation, and wound care. Revive's cannabinoid pharmaceutical portfolio focus' on rare inflammatory and liver diseases, which the FDA granted to the Company orphan drug designation for CBD in the treatment of autoimmune hepatitis and in the prevention of prevention of ischemia and reperfusion injury resulting from solid organ transplantation, such as such as liver, kidney, heart and lung transplantation.

For more information, visit: <u>www.ReviveThera.com</u>.

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.

## Revive Therapeutics Ltd. Cautionary Note Regarding Forward-Looking Statements

This news release may contain forward-looking information that is based on certain assumptions and involves known and unknown risks and uncertainties and other factors that could cause actual events to differ materially from current assumptions and expectations. These statements should not be read as guarantees of future performance or results. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements. A more complete discussion of the risks and uncertainties facing the Company appears in the Company's Management's Discussion & Analysis for the period ended June 30, 2017 and continuous disclosure filings, all of which may be viewed on SEDAR (<u>www.sedar.com</u>). 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.

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