

Revive Therapeutics Applies to FDA for Orphan Drug Designation for Treatment of Autoimmune Hepatitis

TORONTO, ONTARIO--(Marketwired – September 27, 2017) – Revive Therapeutics Ltd. ("Revive" or the "Company") (TSX VENTURE: RVV) (OTCQB: RVVTF), a company focused on the research, development and commercialization of novel treatments for serious and unmet medical needs, 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 autoimmune hepatitis ("AIH"), a rare liver disease.

"This orphan drug designation application is an important first step in the commercial development process of cannabidiol for the potential treatment of autoimmune hepatitis," said Craig Leon, Chief Executive Officer of Revive. "We are focused on advancing the research of novel therapies that target the endocannabinoid system, such as the CB1 and CB2 endocannabinoid receptors, and further strengthen our product pipeline with potentially safer and effective treatments for various liver diseases."

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.

The application to the FDA seeking orphan drug designation of cannabidiol for the treatment of AIH follows the announcement that the Company entered into a license agreement with South Carolina Research Foundation ("SCRF"), under which Revive acquired an exclusive license from SCRF to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as cannabidiol, in the treatment of AIH. The research studies from the University of South Carolina, which formed the basis of the patents, demonstrated both *in vitro* and *in vivo* that CBD may act through cannabinoid receptors CB1 and CB2 as well as unique receptors that belong to the transient receptor potential channel vanilloid ("TRPV") subfamily in induction of apoptosis. TRPV members such as TRPV1 or also known as capsaicin receptor or vanilloid receptor 1 ("VR1") have been reported to be expressed on mast cells, dendritic cells, rat peripheral blood mononuclear cells and thymocyte subsets. CBD acting through these unique receptors and with its known safety profile, therefore, may have the potential as a novel anti-inflammatory and/or immunosuppressant therapy which may be used in the treatment for AIH.

AIH is a rare autoimmune disease causing inflammation to the liver, which 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.

About Liver Disease

Liver disease is described by 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 \$19,536 million by 2022.

About Revive Therapeutics Ltd.

Revive Therapeutics Ltd. (TSX VENTURE:RVV) (OTCQB:RVVTF) is focused on the research, development and commercialization of novel treatments for serious and unmet medical needs by identifying and investigating potential therapies targeting the endocannabinoid system, such as cannabinoids, that may be repurposed for new indications, be delivered in a different way, combined with existing drugs, or be developed as new chemical entities. Additional information on Revive is available at www.ReviveThera.com.

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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: the granting of a patent for Bucillamine for the treatment of gout; the potential efficacy and commercial viability of Bucillamine for treatment of gout and Bucillamine for the treatment of Cystinuria; expansion of the Bucillamine clinical testing program; the Company's drug research and development, and commercialization plans; the Company's research, development and commercialization plans for plant-based therapies, including cannabinoids; the timing of operations; and estimates of market 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. The Company 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 Company'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; the Company'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, 2016 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.