## REVIVE THERAPEUTICS LTD. APPLIES FOR ORPHAN DRUG DESIGNATION TO FDA FOR TREATMENT OF RETT SYNDROME

**Toronto, Ontario (October 28, 2014)** – Revive Therapeutics Ltd. (TSXV: RVV) ("Revive" or the "Company") is pleased to announce that it has applied to the US Food & Drug Administration (FDA) for Orphan Drug Designation for REV-003 (Tianeptine) in the treatment of Rett Syndrome. Rett Syndrome is classified as a rare disease by the Office of Rare Diseases of the National Institutes of Health.

The FDA Orphan Drug Designation program provides a special status to drugs intended to treat, diagnose or prevent so-called orphan diseases and disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation may qualify a company for several benefits under the Orphan Drug Act of 1983. These benefits may include a seven-year marketing exclusivity period upon product approval, a U.S. tax credit for certain clinical testing expenses for the orphan drug, written guidance on the non-clinical and clinical studies needed to obtain marketing approval of an orphan drug, waiver of filing fees under the Prescription Drug User Fee Act (PDUFA), and orphan drug grants.

"Our application for Orphan Drug Designation in the U.S. is a major step in the commercial development process of REV-003 for the treatment of Rett Syndrome," said Fabio Chianelli, Chief Executive Officer of Revive. "This application follows the previously announced positive pre-clinical results evaluating the potential therapeutic effects of REV- 003 on the respiratory activity of an animal model of human Rett Syndrome. In the study, REV-003 had a significant stimulatory effect on the respiratory activity, approximately 20% (p < 0.05), in an animal model of human Rett Syndrome."

Rett Syndrome is a rare neurodevelopmental disorder that affects girls almost exclusively. Children with Rett syndrome develop a number of symptoms that include breathing difficulties, seizures, cognitive disabilities, and loss of motor control. The incidence of Rett Syndrome is estimated at 1 in 10,000 females; in the United States, approximately 16,000 children and women are affected. There is no cure for Rett Syndrome.

## **About Revive Therapeutics Ltd.**

Revive Therapeutics Ltd. (TSXV: RVV) is focused on acquiring, developing and commercializing treatments for major market opportunities such as gout, Rett Syndrome, a rare disease, and post-operative pain. Revive aims to bring drugs to market by finding new uses for old drugs, also known as drug repurposing, and improving the therapeutic performance of existing drugs for underserved medical needs. Additional information on Revive is available at www.revivethera.com.

For more information please contact: Fabio Chianelli

Chief Executive Officer Revive Therapeutics Ltd. Tel: 905-605-5535 (ext. 10) Email: fabio@revivethera.com

Website: www.revivethera.com

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This news release includes certain information and statements about management's view of future events, expectations, plans and prospects that constitute "forward looking statements", which are not comprised of historical facts. 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 eligibility of REV-003 for FDA Orphan Drug status, the potential benefits to the Company of receiving such a designation, the Company's drug research and development plans, and the timing of operations. 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. 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 forwardlooking statements contained herein, management has assumed that it has accurately assessed REV-003's eligibility for FDA Orphan Drug status, 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. Factors that may cause actual results to differ materially from those anticipated by these forward looking statements include: the need to satisfy regulatory and legal requirements with respect to obtaining Orphan Drug status for REV-003; uncertainties associated with obtaining regulatory approval to perform clinical trials and market products; as well as 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; and other factors as described in detail in Revive's Annual Information Form for the period ended June 30, 2014 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.

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