

## **REVIVE THERAPEUTICS ANNOUNCES US FDA GRANTS ORPHAN DRUG DESIGNATION FOR BUCILLAMINE FOR THE TREATMENT OF CYSTINURIA**

TORONTO, ONTARIO--(Marketwired - October 26, 2015) - Revive Therapeutics Ltd. ("Revive" or the "Company") (TSX VENTURE:RVV) today announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration (US FDA) has granted orphan designation status for the use of the drug Bucillamine for the treatment of cystinuria. Orphan drug designation is granted to therapeutics treating rare diseases affecting less than 200,000 people in the U.S. The orphan drug designation qualifies Revive for various incentives such as a seven-year period of marketing exclusivity in the U.S., the potential for expedited drug development, and opportunities for drug grants and assistance in clinical research study design from the U.S. FDA.

"We are pleased to receive the orphan drug designation for Bucillamine in the treatment of cystinuria from the U.S. FDA and with this designation it allows us to evaluate a number of options for further clinical development and/or access of Bucillamine to patients with cystinuria," commented Fabio Chianelli, Chief Executive Officer of Revive. "This milestone allows us to confidently commercialize Bucillamine for the treatment of cystinuria that it is estimated to have a potential market opportunity of \$250 million annually. The orphan drug designation will provide a seven-year period of marketing exclusivity in the U.S. to Revive."

Cystinuria is a rare autosomic recessive genetic disorder that causes high levels of cysteine in the urine thus causing kidney stones to form. This can lead to significant morbidity in affected patients due to the often large and recurrent resulting kidney stones. There are approximately between 10,000 and 12,000 patients affected with cystinuria in the U.S and a worldwide prevalence of one in 7,000.

Current drugs approved by the US FDA for the treatment of cystinuria include Cuprimine® (D-penicillamine), which is a registered trademark of Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) and Thiola® (Tiopronin), which is marketed by Retrophin, Inc. (NASDAQ: RTRX). Both patent protection and the seven-year period of marketing exclusivity from the orphan drug designation for Cuprimine® and Thiola® have expired. Since the approval of Thiola® in 1988, there have been no significant improvements in the treatment of cystinuria.

Revive is focused on commercializing Bucillamine as a potential treatment option in cystinuria. Bucillamine is an oral small molecule drug, which has a chemical structure similar to Thiola®, but has two thiol groups versus the one for Thiola®. In an experimental, comparative in vitro and in vivo study (Koide et. al.) of Bucillamine versus Thiola® in three patients, it was found that the relative activity of Bucillamine was 5% to 12% stronger than that of Thiola® and the relative molecular activity was 40% to 50% stronger than that of Thiola®. From these results, it is theorized that Bucillamine because of its two thiol groups may potentially be an improvement over Thiola® for treatment of cystinuria (*Source: T. Koide, M. Utsunomiya, S. Yamaguchi, T. Yoshioka. A new*

*therapeutic agent for cystinuria, Urolithiasis 2: 571-574, Plenum Press, New York, NY 1994).* Although these results provide only proof of concept and the therapeutic potential of Bucillamine, the long-term efficacy, safety and tolerance of Bucillamine in patients with cystinuria will need to be evaluated in well-controlled clinical trials.

### **About Revive Therapeutics Ltd.**

Revive Therapeutics Ltd. (TSX VENTURE:RVV) is focused on commercializing treatments for gout, and orphan drug indications such as Cystinuria, Wilson disease and Rett syndrome. Additional information on Revive is available at [www.ReviveThera.com](http://www.ReviveThera.com).

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### **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 granting of a patent for REV-002; the potential efficacy and commercial viability of REV-002 for treatment of gout and Bucillamine for the treatment of cystinuria; expansion of the REV-002 clinical testing program; the Company's drug research and development plans; 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. 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. 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 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](http://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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