## REVIVE THERAPEUTICS LTD. SUBMITS PRE-IND PACKAGE TO THE US FDA FOR ITS GOUT DRUG CANDIDATE, REV-002

**Toronto, Ontario** (June 5, 2014) Revive Therapeutics Ltd. (TSXV: RVV) ("**Revive**") announced today that it has submitted a pre-Investigational New Drug (pre-IND) package to the U.S. Food and Drug Administration (FDA) for its gout drug candidate, REV-002.

The submitted pre-IND package provides the FDA with information on Revive's REV-002, as well as a clinical trial plan for a proposed U.S. clinical trial. The FDA's response to the pre-IND package will serve as a guide to Revive's preparation of a full IND application.

This pre-IND submission follows Revive's recently announced meeting request letter submitted to the FDA and its announcement that it has signed a material transfer agreement (the "MTA") with a global pharmaceutical company headquartered in Osaka, Japan. The MTA has allowed Revive to obtain access to confidential information and clinical trial supply of REV-002 for a US-based trial.

Fabio Chianelli, Chief Executive Officer of Revive Therapeutics Ltd., commented, "I am very pleased with this accomplishment as it paves the way for Revive's second product scheduled for a human clinical trial and its first product for a human clinical trial in the U.S., the largest market for gout related products."

## **About Gout**

There were 14.3 million diagnosed prevalent cases of chronic gout in the major pharmaceutical markets in 2012, which is forecast to increase to 17.7 million by 2021 (Source: *Decision Resources 2012*). The prevalence of gout in the U.S. affects approximately 8.3 million (4%) Americans and the prevalence of increased uric acid levels (hyperuricemia) affects 43.3 million (21%) adults in the U.S. (Source: <u>Arthritis Rheum.</u> 2011 Oct;63(10):3136-41). It is estimated that the gout disease treatment market value will increase from \$989 million in 2013 to \$2.28 billion by 2018 (Source: *GlobalData 2014*). Gout is a painful disorder caused by elevated serum uric acid (sUA) in the body due to under excretion of uric acid and/or over production of uric acid. A recent study suggested that only 43% of patients on current standard of care treatment achieved target goals for sUA (<6mg/dL) (Source: *the LASSO study, 2013*). Elevated levels of sUA may lead to acute attacks of severe pain, such as flares and inflammation. Accordingly, there is a need in the market for a therapy to control both sUA and inflammation.

## About REV-002

REV-002 is bucillamine being repurposed by Revive as a potential new treatment for gout. Bucillamine is a disease-modifying anti-rheumatic drug, which is prescribed for rheumatoid arthritis in Japan and South Korea. In animal studies, it has been shown that bucillamine had a synergistic effect in combination with allopurinol in lowering circulating uric acid. In addition, REV-002 offers the opportunity to address the acute flares in gout.

## **About Revive Therapeutics Ltd.**

Revive Therapeutics Ltd. is a Canadian public company (TSX VENTURE: RVV) focused on acquiring, developing and commercializing treatments for major market opportunities such as gout, postoperative pain, and rare diseases. Revive aims to bring drugs to market by finding new uses for old drugs, also known as drug repurposing or drug repositioning, and improving the therapeutic performance of existing drugs for underserved medical needs. Additional information on Revive is available at <a href="https://www.revivethera.com">www.revivethera.com</a>.

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

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