

REVIVE THERAPEUTICS ANNOUNCES POSITIVE FINAL RESULTS FROM ITS PHASE 2A STUDY FOR THE TREATMENT OF ACUTE GOUT FLARES

TORONTO, ONTARIO--(Marketwired - December 1, 2015) - Revive Therapeutics Ltd. ("Revive" or the "Company") (TSX VENTURE:RVV) (OTCQB:RVVTF), a company focused on commercializing treatments for gout, and rare diseases such as Cystinuria, Wilson's disease and Rett syndrome, today announced positive final results from its phase 2a proof-of-concept clinical study of REV-002 (Bucillamine), an oral anti-inflammatory agent, for the treatment of acute gout flares.

"I am very pleased with the clinical results as it provides justification for expanding our clinical and commercialization prospects for Bucillamine in the treatment of acute gout flares," said Fabio Chianelli, Chief Executive Officer of Revive. "In the study, Bucillamine was as good or better as compared to Colchicine, a gout drug in the U.S. with reported sales of \$688 million for the 12 months ended August 2014 according to IMS Health. This early validation paves the way for a Phase 2b clinical study, which would be used as part of the new drug application to the FDA to seek approval of Bucillamine for the treatment of acute gout flares in the U.S."

The objective of the Phase 2a study was to evaluate the safety and tolerability, and the efficacy of two regimens of oral Bucillamine over seven days of treatment compared with Colchicine (Colcrys®) in the treatment of subjects with severe gout flare attack. The primary efficacy endpoint is the proportion of patients who responded to treatment defined as a $\geq 50\%$ reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug.

The final primary endpoint results from the Phase 2a study from a total of 74 subjects that had completed the seven-day treatment period are as follows:

- In Arm A (oral Bucillamine – total of 900mg over 7 days), 55% (12/22 subjects) had a $\geq 50\%$ reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug;
- In Arm B (oral Bucillamine – total of 1,800mg over 7 days), 46% (11/24 subjects) had a $\geq 50\%$ reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug;
- In Arm C, the active comparator arm, (oral Colchicine - 1.8mg over 1 hour), 46% (13/28 subjects) had a $\geq 50\%$ reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug; and
- Bucillamine was well tolerated and there were no serious adverse events reported in subjects taking Bucillamine.

"Bucillamine for the treatment of acute gout flares has a clear pathway to regulatory approval in the U.S., based on previously approved drugs by the FDA for this indication," said Dr. Lee Simon, senior clinical and regulatory affairs advisory to Revive. "These exploratory results reported above demonstrate that Bucillamine has a signal of efficacy similar to that observed with the comparator drug, Colchicine (Colcrys®), in this clinical

study, which has been previously approved for this indication in the U.S. As a result, Revive is actively planning a potentially pivotal Phase 2b, adequate and well-controlled, multicenter, double blinded, placebo controlled trial. It is important to note, that in the U.S., regulatory approval requires a drug to be superior to placebo in the statistical analysis and to demonstrate this difference from placebo is clinically relevant in two replicate studies.”

About the Phase 2a Proof-of-Concept Study

The Phase 2a study is an open-label, multicenter, active-controlled, parallel-group clinical trial designed to evaluate the safety and efficacy of two arms of Bucillamine 100mg tablet compared with the active comparator Colchicine (dosed acutely using the FDA-approved regimen) in the treatment of subjects with acute gout flares over a seven-day treatment period. A total of 20 clinical sites in the United States participated in the study and a total of 74 subjects who are confirmed with a qualifying severe gout flare attack was randomized into the study. Subjects were randomized in a 1:1:1 allocation ratio to either Arm A (oral Bucillamine – total of 900mg), Arm B (oral Bucillamine – total of 1,800mg) or Arm C (oral Colchicine – total of 1.8mg) over a seven-day treatment period.

The primary efficacy endpoint is the proportion of patients who responded to treatment. Treatment responders are defined as a $\geq 50\%$ reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug. The target joint pain score is an 11-point Pain Intensity Numeric Rating Scale (PI-NRS) used to assess joint pain intensity while experiencing a gout flare on a scale from 0 (no pain) to 10 (worst possible pain). The PI-NRS is completed using a diary where the subject is required to circle the most appropriate number that best describe their level of pain in the identified target joint during specific time points.

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*). Gout in the U.S. affects approximately 8.3 million (~3.9%) of American adults (Source: *Arthritis Rheum.* 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. Most patients on the most commonly employed regimens for uric acid lowering fail to achieve a satisfactory serum urate level. Poor control of gout can lead to acute attacks of severe pain, and chronic joint damage and impairment of health related quality of life. Accordingly, there are needs in the market for new therapies to control gouty inflammation and hyperuricemia.

Although gout is a treatable condition, there are limited treatment options, many of which have adverse side effects. Drug treatment for gout includes anti-inflammatory agents (non-steroidal anti-inflammatories (NSAIDs), corticosteroids, Colchicine) and serum urate-lowering therapies, which work by lowering body stores of uric acid. Treatment of gouty inflammation is complicated by the fact that gout patients have a high incidence of cardiovascular and metabolic comorbidities. Common comorbidities include hypertension (70-80%), coronary artery disease (>30-40%), chronic kidney disease (~30-50%), diabetes (~25-40%), gastrointestinal tract diseases, and congestive heart failure (Source: Keenan, RT et. al., *Prevalence of contraindications and prescription of pharmacologic therapies for gout. Am. J. Med. 2011, 124: 155-163*). Managing patients with these comorbidities is challenging because the majority of them have contraindication for one or more first-line approved medications to treat acute gout. Current drug therapy limitations include: 90% of gout patients having at least one contraindication to NSAIDs and glucocorticoids; 50% to 66% having at least one contraindication to Colchicine. Moreover, corticosteroids can cause hypertension and worsening of blood sugar, and NSAIDs have substantial renal and cardiovascular toxicity.

About REV-002 (Bucillamine)

REV-002 (Bucillamine) is being developed by Revive as a potential new treatment for acute gout flares. Bucillamine is a disease-modifying anti-rheumatic drug, which is prescribed for rheumatoid arthritis in Japan and South Korea.

About Revive Therapeutics Ltd.

Revive Therapeutics Ltd. (TSX VENTURE:RVV) (OTCQB:RVVTF) is focused on commercializing treatments for gout, and rare diseases such as Cystinuria, Wilson's disease and Rett syndrome. 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@revivetherapeutics.com
Website: www.revivetherapeutics.com

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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, including REV-003 (Tianeptine) for the treatment of Rett Syndrome and REV-005 (Bucillamine) for the treatment of Wilson's Disease; 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 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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