REVIVE THERAPEUTICS ANNOUNCES POSITIVE INTERIM RESULTS FROM PHASE 2A STUDY OF REV-002 (BUCILLAMINE) IN THE TREATMENT OF ACUTE GOUT FLARES

TORONTO, ONTARIO--(Marketwired - September 30, 2015) - Revive Therapeutics Ltd. ("Revive" or the "Company") (TSX VENTURE:RVV) today announced interim results from the ongoing Phase 2a clinical study evaluating REV-002 (Bucillamine) as an oral anti-inflammatory agent for the treatment of acute gout arthritis flares.

The interim results from the Phase 2a clinical study yielded the following key findings in 29 subjects treated for acute gout flare that had completed the 7-day treatment period:

- In Arm A (oral Bucillamine - 900mg over 7 days), 25% (2/8 subjects) had a ≥ 50% reduction in target joint pain score from baseline at 72 hours post-dose;
- In Arm B (oral Bucillamine - 1,800mg over 7 days), 67% (6/9 subjects) had a ≥ 50% reduction in target joint pain score from baseline at 72 hours post-dose;
- For the active comparator Arm C (oral Colchicine - 1.8 mg over 1 hour), 42% (5/12 subjects) had a ≥ 50% reduction in target joint pain score from baseline at 72 hours post-dose; and
- No related serious adverse events were reported in any of the treatment arms.

"We are encouraged to see potential efficacy of the higher dose Arm B of oral Bucillamine in the Phase 2a study results to date," said Fabio Chianelli, Chief Executive Officer of Revive. "More results will be forthcoming as the clinical study moves forward, but evidence of efficacy of Bucillamine as the dose increases and the preliminary results for tolerance of the higher dosing arm of Bucillamine support the potential of Bucillamine as an anti-inflammatory agent for treatment of acute gout flares. Revive is at a major inflection point in its life cycle and I am very pleased with the interim data as it serves as an important value-creating milestone for Revive and it provides support for expanding our clinical program and commercialization prospects for REV-002 in the treatment of gout."

About the Study

The ongoing Phase 2a study is an open-label, multicenter, active-controlled, parallel-group clinical trial designed to evaluate the safety and efficacy of two doses of Bucillamine 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. At up to a maximum of 20 clinical sites in the United States, the study aims to enroll sixty-six eligible subjects, who are confirmed with qualifying gout flare, and who will be randomized in a 1:1:1 allocation ratio to either Arm A (Bucillamine - 900mg), Arm B (Bucillamine - 1,800mg) or Arm C (Colchicine - 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 ≥ 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, for example at 24 hours, 48 hours, and 72 hours post-dose.

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 many of them are contraindicated for medications currently available to treat gout. For example, corticosteroids can cause hypertension and worsening of blood sugar, and NSAIDs have substantial renal and cardiovascular toxicity. A majority of gout patients harbor moderate to strong contraindications to multiple first-line gout treatment medications.

About REV-002 (Bucillamine)

REV-002 (Bucillamine) is being developed 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. REV-002 is being evaluated in a Phase 2a clinical study in subjects with acute gout flares in the U.S.

About Revive Therapeutics Ltd.

Revive Therapeutics Ltd. (TSX VENTURE:RVV) is a clinical-stage company 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.

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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 potential efficacy and commercial viability of REV-002 for treatment of gout; 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*). 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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