

REVIVE THERAPEUTICS LTD. ANNOUNCES INITIATION OF A PHASE 2A STUDY OF REV-001 (TIANEPTINE) FOR THE PREVENTION OF OPIOID-INDUCED RESPIRATORY DEPRESSION

Toronto, Ontario (January 15, 2014) Revive Therapeutics Ltd. (TSXV:RVV) (“**Revive**”) announced today that the initiation of a Phase 2a proof of concept study of REV-001 (tianeptine), for the prevention of opioid-induced respiratory depression, is well underway. The study is being conducted at the Leiden University Medical Center in The Netherlands under the supervision of Prof. Dr. Albert Dahan, M.D., Ph.D.

The Phase 2a proof-of-concept study of REV-001 is a placebo-controlled, double-blind, randomized two-way crossover study in healthy adult subjects. The study is designed to evaluate the effect of an oral dose of tianeptine on alfentanil-induced respiratory depression and antinociception. The study will be performed in 16 healthy male and female volunteers in the age group of 18-35 years. Each subject will be tested twice, once during the infusion of alfentanil following placebo, and once during the infusion of alfentanil following an oral dose of tianeptine. The first cohort (8 subjects) will receive 37.5 mg tianeptine and the second cohort (8 subjects) will receive either 25 mg or 50 mg. An analysis of the first cohort will be performed to assess the magnitude of effect. If the reversal effect in the first cohort is greater than 75% (in terms of increase in slope of the ventilator response to CO₂ during alfentanil infusion relative to baseline values) the second cohort will be treated with an oral dose of 25 mg tianeptine; if the reversal is less than 75% the second cohort will be treated with an oral dose of 50 mg tianeptine.

"We are pleased that the initiation of the first cohort of 8 subjects has occurred, marking an important milestone for Revive," said Fabio Chianelli, Revive's Chief Executive Officer. "We aim to position REV-001 as a novel therapy for the prevention of post-operative opioid-induced respiratory depression in patients with sleep apnea."

About REV-001 (Tianeptine)

REV-001 is the repurposing of the drug tianeptine, an old but unique anti-depressant drug, which is marketed in Asia, parts of Europe (e.g. France) and South America. Despite its narrow geographic scope, the decades-long clinical experience of tianeptine suggests much about its safety. In fact, tianeptine has been shown to have substantial cardiovascular and other safety at both normal doses and in overdose. (Source: Wilde, M. I. & Benfield, P. *Drugs* 49, 411–439 (1995)). More recently, tianeptine was shown for the first time to prevent opioid(morphine)-induced respiratory depression in an animal model. The novel findings in the study enabled Revive to apply for intellectual property protection covering the use of tianeptine to treat respiratory depression.

About Sleep Apnea and Opioid-induced respiratory depression

According to the Centers for Disease Control and Prevention, approximately 70 million people in the United States are affected by sleep disorders, such as obstructive sleep apnea (“**OSA**”). The risk of perioperative complications increase substantially with those who have OSA. With 51.4 million inpatient surgical procedures performed annually (2010) in the U.S. (Source: <http://www.cdc.gov/nchs/fastats/insurg.htm>), hospitals must take into consideration the financial implications that may become prevalent for patients who have OSA in order to reduce the risk of adverse events, such as opioid-induced respiratory depression. It has been estimated that between 29% and 41% are at high risk of opioid-induced respiratory depression. (Source: Hanna MH et al. *Anesthesiology*. 2005;102(4): 815-821 and Overdyk FK et al. *Anesth Analg*. 2007;105(2): 412-418). Currently, there are no approved drugs for OSA and the only drug treatments to counter opioid-induced respiratory depression is to administer opiate receptor antagonists such as naloxone (Narcan®). However, those antagonists eliminate the analgesic activity of the opioid drug and thus are rarely used by hospitals and healthcare facilities to prevent or treat opioid-induced respiratory depression. According to an article published in the *New England Journal of Medicine* in June 2013, perioperative sleep apnea in the United States has been considered as an ‘Epidemic’.

About Revive Therapeutics Ltd.

Revive Therapeutics Ltd. is a Canadian public company (TSXV:RVV) focused on acquiring, developing and commercializing treatments for major market opportunities such as sleep apnea, gout and rare diseases. 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.revivetherapeutics.com.

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