





Combination of Morphine plus Oxycodone IV Demonstrates Improved Analgesia and Tolerability Compared to IV Morphine

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today positive results of its Phase 2 comparative proof-of-concept study to evaluate the efficacy and safety of its IV (intravenous) formulation of morphine plus oxycodone versus IV morphine alone for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery. The main findings demonstrated that QRxPharma's formulation of MoxDuo IV resulted in fewer side effects and offered better pain relief than morphine alone.

"We are pleased to announce the encouraging data from this comparative study as it represents yet another important milestone demonstrating the significant efficacy and improved safety of our MoxDuo product portfolio across multiple Dual Opioid<sup>®</sup> formulations," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma.

This double blind, active controlled, investigator initiated study was conducted in Germany in collaboration with QRxPharma at the Cologne-Merheim Medical Center, University Hospital of the Witten/Herdecke University, and Cologne University Hospital. 40 patients were randomised into two treatment groups—morphine plus oxycodone IV or morphine IV – after undergoing total hip replacement surgery and developing moderate to severe pain. The study consisted of two periods: a 65 minute dose-titration phase in which fixed doses were given once every 5 minutes until a strong analgesic effect occurred, and then a 47 hour patient controlled analgesia (PCA) phase in which patients could self administer a fixed amount of study drug as frequently as once every 6 minutes.

Primary endpoints determined whether: (1) intravenous co-administration of morphine and oxycodone (Dual Opioid) had fewer opioid-related adverse events than morphine alone at equi-analgesic doses and (2) Dual Opioid provided a different analgesic response than morphine alone.

During the initial 65 minute dose-titration period, the primary endpoint for evaluating efficacy was the difference in the sum of pain intensity (SPID) scores from baseline for each patient. Over this period, SPID<sub>65 min</sub> scores were 50% higher (i.e. 50% better pain relief/analgesic efficacy) among patients in the Dual Opioid IV study group compared to

those receiving morphine alone. 67% of patients receiving Dual Opioid IV dosing reported good to excellent global improvement (i.e. experienced good to very good pain relief) compared to 53% of those receiving morphine alone.

During the entire 48 hour study period (dose titration plus PCA period), SPID<sub>48</sub> scores were 10% higher among patients in the Dual Opioid IV study group compared to those receiving morphine alone. PCA data also indicated that patients in the Dual Opioid IV study group were able to achieve better pain relief faster and with less drug (13 IV doses of Dual Opioid vs. 17 doses of morphine IV).

Dual Opioid IV product dosing was well tolerated, with nausea and vomiting being the most common adverse events. For Dual Opioid dosing, 24% of patients experienced mild nausea and 5% experienced moderate to severe nausea compared to 53% experiencing mild nausea and 11% experiencing moderate to severe nausea on morphine alone. 10% of patients receiving Dual Opioid IV experienced mild vomiting and zero incidences of severe vomiting were reported compared to 16% of patients receiving morphine alone who experienced mild vomiting and 11% who experienced moderate to severe vomiting. These results are consistent with a continually growing body of data from both QRxPharma generated clinical trials (5 studies) and outside investigators (5 studies), demonstrating better pain control with at least a 50% reduction of these clinically significant opioid induced adverse events when Dual-Opioid therapy is used.

Among patients receiving Dual Opioid IV, none experienced low blood oxygen levels (SPO<sub>2</sub><90%), whereas 16% of patients on morphine experienced oxygen desaturation. These results indicate less risk of respiratory depression with Dual Opioid IV.

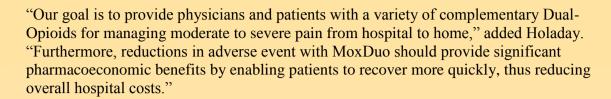
Professor Edmund Neugebauer, Chair of Surgical Research and Director of the Institute for Research in Operative Medicine noted "This study extends the body of research on MoxDuo for pain relief with a superior side effect profile in patients in the immediate postoperative period. I have had a long interest in postoperative pain management and I am pleased that the study adds to the development of a beneficial product in the field."

The Company is working to bring to market complementary analgesic options for pain specialists that achieve greater patient tolerability and analgesic efficacy than current standards of care. MoxDuo IV is one of three Dual-Opioid products that also include immediate release (IR) and controlled release (CR) oral formulations. "The results of this study parallel what we have seen with the oral formulation, MoxDuo IR, which delivers both a superior analgesic effect and a significantly better side effect profile compared to morphine alone" said Holaday. "When compared at equal analgesic doses, MoxDuo IR can reduce the occurrence of moderate to severe nausea and vomiting by 50-100%, and opens the therapeutic window for pain relief."









In February 2010, QRxPharma and Aoxing Pharmaceutical Company (NYSE AMEX: AXN) announced a strategic alliance to collaborate in the development of MoxDuo IV. Under the terms of the agreement, Aoxing will fund the development of MoxDuo IV for the China market in exchange for exclusive marketing rights in China. QRxPharma will retain ownership of MoxDuo IV and may use the clinical and preclinical work completed by Aoxing for product registration and commercialisation outside of China.

###

For more information please contact:

Dr John W Holaday Managing Director and Chief Executive Officer Tel: +1 301 908 3086

Email: john.holaday@qrxpharma.com

Chris J Campbell
Chief Financial Officer and Company Secretary

Tel: +61 2 9492 8021

Email: chris.campbell@grxpharma.com

## **Forward Looking Statements**

This release contains forward-looking statements. Forward-looking statements are statements that are not historical facts; they include statements about our beliefs and expectations. Any statement in this release that states our intentions, beliefs, expectations or predictions (and the assumptions underlying them) is a forward-looking statement. These statements are based on plans, estimates and projections as they are currently available to the management of QRxPharma. Forward-looking statements therefore speak only as of the date they are made, and we undertake no obligation to update publicly any of them in light of new information or future events. By their very nature, forward-looking statements involve risks and uncertainties. A number of important factors could therefore cause actual results to differ materially from those contained in any forward-looking statement. Such factors include risks relating to the stage of products under development; uncertainties relating to clinical trials; dependence on third parties; future capital needs; and risks relating to the commercialisation of the Company's proposed products.

## **About QRxPharma**

QRxPharma (ASX: QRX and OTCQX: QRXPY) is a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management and central nervous system (CNS) disorders. Based on a development strategy which focuses on enhancing and expanding the clinical utility of currently marketed compounds, the Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, and improved patient outcomes. The Company intends to co-promote its products in the US and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, MoxDuo<sup>®</sup>IR, is in Phase 3 clinical development and has successfully completed multiple comparative studies evaluating its efficacy and safety against equi-analgesic doses of morphine, oxycodone and Percocet<sup>®</sup> for the treatment of acute pain. QRxPharma expects to complete its Phase 3 program in Q4 CY2010 and file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) for MoxDuo IR in Q1 CY2011. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit www.grxpharma.com.