

## ASX RELEASE

14 June 2011

## **QRxPharma Completes Comparative Safety Study**

At equi-analgesic doses, MoxDuo<sup>®</sup> IR produced less respiratory depression than Morphine or Oxycodone

Sydney, Australia and Bedminster, New Jersey -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the successful completion of Study 022, an exploratory Phase 3 study comparing the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone. The primary endpoint of respiratory depression as measured by oxygen desaturations, a medically important, opioid-related adverse event, was less severe and of shorter duration in patients receiving MoxDuo (12 mg/8 mg) compared to those receiving equi-analgesic doses of either morphine (24mg) or oxycodone (16 mg) alone. Respiratory depression is the leading cause of death from high doses of opioids. Moderate to severe vomiting was also less frequent in the MoxDuo patients when compared to oxycodone. This double-blind, randomized, fixed dose trial enrolled 375 patients with moderate to severe postoperative pain following bunionectomy surgery at 4 US clinical research sites.

"We are excited that the results of this study demonstrated that MoxDuo treated patients, while receiving effective pain relief, experienced less severe respiratory depression, which is a major safety advantage," said Dr. John Holaday, Managing Director and CEO. "The study also provided a wealth of information, enabling us to optimise the designs of future trials to support our comparative safety claim program. MoxDuo's favourable side effect profile, when compared head-to-head to current standards of care, distinguishes the product from other acute pain opioids in the clinical marketplace. To the best of our knowledge, MoxDuo is the first opioid product to demonstrate a lower risk of respiratory depression in a clinical study comparing morphine equivalent doses."

Episodes of respiratory depression are a commonly reported and expected side effect associated with use of opioid analgesics. Such events are clinically measured by changes in blood oxygenation (pulse oximetry -SpO $_2$ ). In this study, measures of insufficient blood oxygenation (oxygen desaturation SpO $_2$ <90%) over time to assess both the severity and duration of respiratory impairment indicated that MoxDuo has a significantly better (p<0.02) safety profile than oxycodone. Beneficial trends for MoxDuo also occurred in comparisons to morphine treatment on these same endpoints.



In addition, the secondary endpoints of opioid related side effects were consistent with previous studies demonstrating that the occurrence of moderate to severe vomiting was significantly (p<0.04) reduced (32% vs. 42%) in MoxDuo IR treated subjects compared to patients receiving oxycodone alone at the same 24 mg morphine equivalent dose. Morphine and MoxDuo had comparable rates of moderate-severe vomiting. In respect to nausea, the overall incidence of this treatment emergent adverse event trended lower in the MoxDuo treated subjects than oxycodone and morphine, but the differences were not statistically significant.

Approximately 40% of the enrolled subjects were age 60 years or older (range 60-79), thus demonstrating MoxDuo's advantageous safety profile across a broad section of the patient population needing effective management of moderate to severe pain. Such results provide valuable safety and efficacy information for addressing regulatory requirements for future MoxDuo product labelling.

These exploratory findings will be submitted as part of a 2011 product registration filing with the US Food and Drug Administration (FDA) and will also be supportive of QRxPharma's European Marketing Authorisation Application (MAA) scheduled for submission in the first half of 2012. When published in the medical literature, these results may, in conjunction with other trial data, positively impact the commercial launch of MoxDuo IR projected for the US in 2012 and for Europe in 2013.

The Company continues to expect to file a New Drug Application (NDA) with the FDA for MoxDuo IR within the next two months. MoxDuo IR capsules are a patented 3:2 fixed ratio combination of morphine and oxycodone that targets the acute pain market, a \$2.5 billion segment of the \$7 billion spent annually on prescription opioids in the US.

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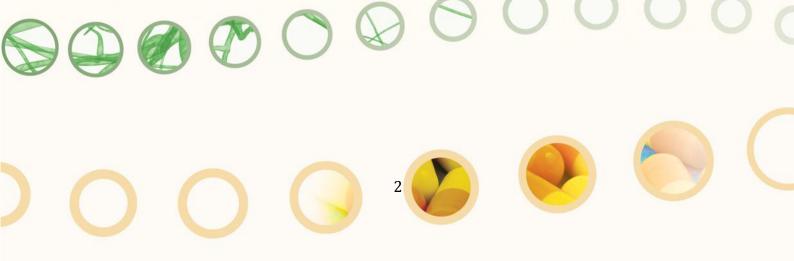
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## **About QRxPharma**

QRxPharma Limited (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 that 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, immediate release MoxDuo, has successfully completed pivotal Phase 3 studies and the Company expects to file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) in mid-2011. The Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit www.qrxpharma.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.