

ASX RELEASE 27 April 2011

## QRxPharma Completes Patient Enrolment of MoxDuo<sup>®</sup>IR Phase 3 Comparative Safety Study

Evaluated Tolerability and Safety Advantages of MoxDuo IR Compared to Equi-Analgesic

Doses of Morphine and Oxycodone

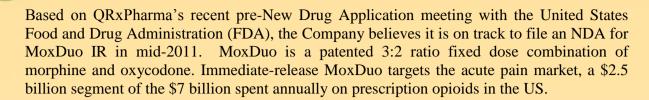
**Sydney, Australia and Bedminster, New Jersey** -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today it has completed patient enrolment for Study 022, a Phase 3 trial comparing the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone. Specifically, the study evaluated the incidence of opioid-related adverse events – including changes in respiratory function, moderate to severe nausea, vomiting and dizziness – in patients with moderate to severe postoperative pain following bunionectomy surgery. The trial enrolled 375 patients (n=125 per treatment group) at 5 US clinical research sites. QRxPharma expects to release top-line data in June.

"This Phase 3 trial represents a major milestone as it is the first comparison MoxDuo IR (12 mg/8 mg) to equi-analgesic doses of morphine and oxycodone," said Dr. John Holaday, Managing Director and CEO, QRxPharma. "With patient enrolment complete, we are optimistic that the pending results will confirm the significant tolerability and safety advantages of MoxDuo IR over these two widely prescribed opioids."

A prior comparator study in patients experiencing acute postoperative bunionectomy pain demonstrated the potential side effect and safety benefits of MoxDuo IR (6 mg/4 mg) when compared to equi-analgesic doses of morphine (12 mg) or oxycodone (8 mg). Specifically, the occurrence rate of moderate to severe adverse events including nausea, vomiting and dizziness was reduced by 50-75% in MoxDuo IR treated subjects compared to patients receiving morphine or oxycodone alone at the same 12 mg MED (morphine equivalent dose).

This Phase 3 study was similarly designed, but compared MoxDuo IR (12 mg/8 mg - 24 mg MED) with equi-analgesic doses of morphine (24 mg) and oxycodone (16 mg). By design, approximately 40% of the enrolled subjects were age 60 years or older, thus providing ample evaluation of the tolerability of the three treatments in this age group.

Trial results will form part of QRxPharma's European Marketing Authorisation Application (MAA) scheduled for submission in the first quarter of 2012. Study results, when published in medical literature, may, in conjunction with other trial data, be a component of the promotional package following the projected commercial launch of MoxDuo IR in the US in 2012 and in Europe in 2013.



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## **About QRxPharma Limited**

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 U.S. 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 <a href="https://www.qrxpharma.com">www.qrxpharma.com</a>.

## **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.