



**ASX RELEASE**  
10 February 2010

## **QRxPharma Initiates Second Pivotal Phase 3 Study of MoxDuo™IR Dual-Opioid™ for NDA Submission**

*Evaluate Analgesic Efficacy and Safety of MoxDuo™IR in Patients with Moderate to Severe Post-Operative Pain Following Total Knee Replacement Surgery*

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today initiation of its second pivotal Phase 3 registration trial (Study 009) to evaluate analgesic efficacy and safety of MoxDuo™IR, a patented 3:2 ratio fixed dose combination of morphine plus oxycodone. This two-arm study will compare the effectiveness and safety of a flexible MoxDuo™IR dose regimen to a fixed low dose for managing moderate to severe pain in patients who have undergone total knee replacement surgery. The Company expects to complete dosing in Q3 2010 in preparation for filing a New Drug Application (NDA) with the US Food and Drug Administration in Q4 2010. MoxDuo™IR targets the acute pain market, a \$2.5 billion segment of over \$7 billion spent annually on prescription opioids in the US.

“In support of our Phase 3 program, clinical trials conducted to date have consistently demonstrated MoxDuo™IR achieves as good or better pain relief with fewer incidences of moderate-severe side effects than morphine, oxycodone or Percocet®. Based on these data, we are optimistic about the competitive advantages of MoxDuo,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “With the initiation of the Company’s second pivotal trial for MoxDuo™IR, we are one step closer to definitively proving the value of our Dual-Opioid™ product to potential partners, prescribers and patients.”

In 2009, an open-label pilot study demonstrated improved analgesia of flexible dose MoxDuo™IR (individual doses up to 24mg morphine/16mg oxycodone) compared to fixed, low dose MoxDuo™IR (3mg morphine/2mg oxycodone) in patients with moderate to severe pain following total knee replacement surgery. Based on these results, low dose MoxDuo™IR was selected as the control for this pivotal trial.

Study 009, a randomised, double blind trial, is targeted to enroll 140 patients (70 per study Arm) at 8 US clinical research sites. Initially, all post-operative patients will receive



intravenous patient controlled analgesia (PCA) morphine until the day following knee replacement surgery. At such time, PCA morphine dosing will be stopped. When pain becomes moderate to severe [based on the 10-point Numerical Pain Rating Scale (NPRS)], patients will then be randomised in equal numbers to receive either a flexible regimen of MoxDuo™IR (Arm 1) or the low dose control (Arm 2).

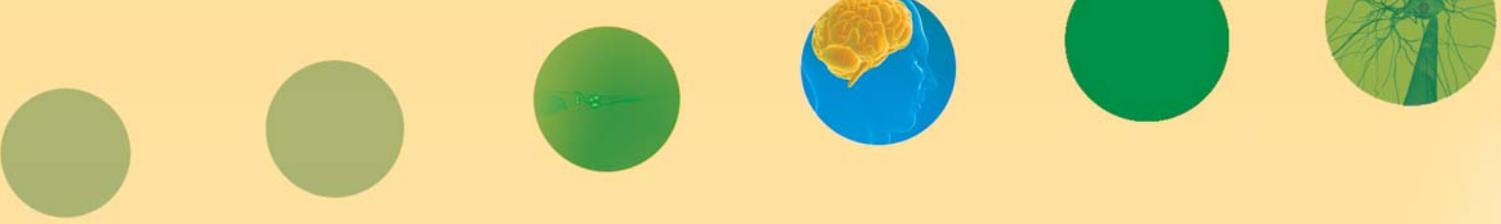
For patients assigned to the flexible dose regimen (Arm 1), the initial dose will be based on the Company's proprietary algorithm (developed in the prior open label study) that converts PCA morphine to oral morphine equivalents of MoxDuo™ IR. All Arm 1 patients will start on at least 12mg/8mg (morphine/oxycodone); patients in Arm 2 will receive a loading dose of 6mg/4mg followed by 3mg/2mg regardless of their initial PCA dosing regimen. All patients will be dosed every four to six hours over a 48-hour period.

The primary endpoint for evaluating the efficacy of flexible dose versus low dose is the difference from baseline in pain intensity scores for each treatment group over the 48-hour treatment period [Sum of Pain Intensity Differences over 48 hours (SPID<sub>48</sub>) calculated using the 10-point NPRS]. Secondary endpoints include: (1) efficacy relating to the time to onset of analgesia and global assessment of effect (i.e. total pain relief) as well as amount of supplemental analgesia used throughout the treatment period; and (2) safety as measured by incidence and intensity of opioid-related adverse effects.

To date, more than 500 patients experiencing pain following different surgical procedures (bunionectomy and total knee replacement) as well as non-surgical patients with chronic pain have received MoxDuo™IR. Study results consistently demonstrate MoxDuo™IR's greater overall tolerability allowing the doctors and patients to achieve as good or better pain relief with substantially fewer incidences of nausea, vomiting, constipation, dizziness, and hypotension. For example, at equal analgesic doses the frequency of moderate to severe adverse events was 50% to 75% lower among patients on MoxDuo™IR than those receiving morphine, oxycodone or Percocet® (oxycodone plus acetaminophen).

In December, 2009, QRxPharma announced the initiation of its first Pivotal Phase 3 (combination rule) study in bunionectomy patients to demonstrate that MoxDuo™IR provides superior analgesia compared to its component doses of morphine and oxycodone. According to the FDA, once these two pivotal studies are completed, no additional pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission and market approval. QRxPharma expects to complete its Phase 3 program in Q3 2010 and file its NDA for MoxDuo™IR by the end of year 2010.

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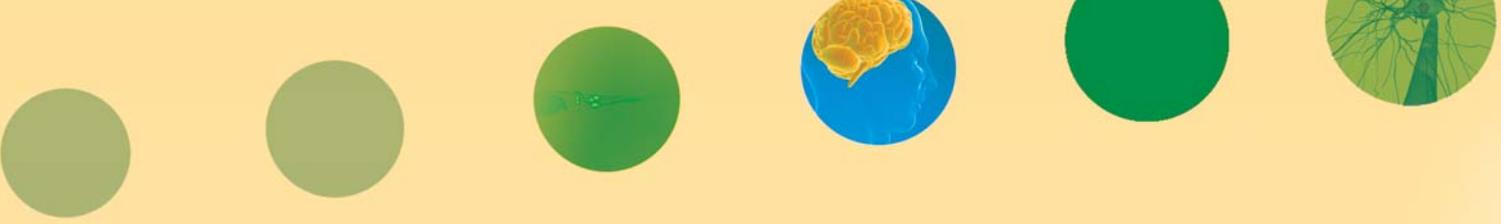
### **Forward Looking Statements**

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 therapies for pain management and central nervous system (CNS) disorders. Based on a business strategy to expand the clinical utility and commercial value of marketed and/or existing compounds, QRxPharma's product portfolio includes both late and early stage clinical drug candidates with well-defined paths to regulatory approval and sales. The Company intends to directly commercialise its products in the US and seek strategic partnerships for worldwide markets.



QRxPharma's lead compound, MoxDuo™IR (Q8003IR), is in Phase 3 clinical development and has successfully completed multiple comparative studies evaluating its efficacy and safety against equianalgesic doses of morphine, oxycodone and Percocet® for the treatment of acute pain. Study results consistently demonstrate MoxDuo™IR's greater overall tolerability, achieving as good or better pain relief with substantially fewer incidences of moderate to severe side effects. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information: [www.QRxPharma.com](http://www.QRxPharma.com).