

ASX RELEASE 30 November 2009

QRxPharma Initiates Pivotal Phase 3 Study of MoxDuo[™]IR For Moderate to Severe Acute Pain

Combination Rule Study to Compare Analgesic Efficacy and Safety of MoxDuo[™]IR with Oxycodone and with Morphine in Patients with Post-Surgical Pain

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today, as part of its Phase 3 program, the initiation of a registration (also called pivotal) trial (Study 008) comparing efficacy and safety profiles of MoxDuo[™]IR against component doses of morphine and oxycodone alone for the management of moderate to severe post-operative pain following bunionectomy surgery. The Company expects to complete dosing by close of Q2 2010.

"We recently reported clinical studies demonstrating the superiority of MoxDuoTMIR in terms of tolerability compared to equi-analgesic doses of morphine, oxycodone and Percocet[®] for the management of acute post-operative pain. These studies demonstrated that MoxDuoTMIR provides significant pain relief and fewer side effects (nausea, vomiting, dizziness and constipation)." said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "We are now addressing a regulatory requirement for New Drug Application (NDA) approval of MoxDuoTMIR, i.e., demonstration that it is superior in efficacy to its individual components."

A double-blind study with about 35 patients per group, completed earlier this year in patients with pain following bunionectomy surgery, demonstrated the superiority of MoxDuo 12 mg/8 mg relative to 12 mg morphine and to 8 mg oxycodone. The purpose of the current Phase 3 registration study (008) is to replicate these differences in a larger trial, one with sufficient statistical power to achieve significance on the primary and secondary endpoints. If successful, this trial will satisfy the "Combination Rule" requirement of the US Food and Drug Administration (FDA) and will also serve as a registration study.

This double-blind, randomised and repeat fixed-dose study compares MoxDuoTMIR's reduction in pain intensity (primary endpoint) to component doses of oxycodone and morphine in patients experiencing moderate to severe post-operative pain over 48 hours. The study is targeted to enroll 522 patients (with 174 in each treatment group) at 6 US clinical research sites.

The primary endpoint for evaluating the efficacy of MoxDuoTMIR 12 mg/8 mg versus its milligram components of morphine 12 mg and oxycodone 8 mg administered every six hours is the difference in pain intensity scores for each patient group over the 48-hour treatment period (SPID₄₈ calculated from the 10-point Numerical Pain Rating Scale). Secondary endpoints include: (1) efficacy relating the patient's global assessment of effect (i.e. extent of overall pain relief) as well as amount of supplemental analgesia (acetaminophen) used throughout the treatment period; and (2) safety as measured by incidence and intensity of opioid-related adverse effects. QRxPharma incorporated input from the FDA regarding the design and statistical analysis of this study.

The final Phase 3 registration trial (Study 009: a double-blind controlled study to evaluate the effectiveness of MoxDuoTMIR in patients following total knee replacement surgery) is scheduled to begin Q1 2010. 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 Q3 2010 and file its NDA for MoxDuoTMIR by EOY 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 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.

