



**FOR IMMEDIATE RELEASE**

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## **QRxPharma Releases Additional Phase 3 Data for Q8003IR 'Dual Opioid' Pain Therapy**

*Establishes Preferred Dose for Optimal Efficacy and Tolerability; Study Goals and Secondary Endpoints Met*

Sydney, Australia & Bedminster, New Jersey – QRxPharma Limited (ASX:QRX), a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of therapies for pain and central nervous system (CNS) disorders, announced today additional Phase 3 data for Q8003IR establishing a 12mg/8mg morphine and oxycodone combination as the preferred dose for optimal efficacy and tolerability.

“While the initial Phase 3 efficacy data demonstrated statistically significant pain reduction activity of Q8003IR at all dose levels, further analysis suggests that the 12mg/8mg dose delivers the best analgesic effect and tolerability profile,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “These data confirm that our patented dual opioid combination of morphine and oxycodone provides synergistic effects on pain relief and is able to achieve equal or better analgesia at materially lower doses than the active opioid comparator while simultaneously reducing incidence levels of specific side effects.”

The goal of the double-blind, placebo-controlled Phase 3 study was to compare four different dosage regimens of Q8003IR in patients with moderate to severe post-surgery pain (bunionectomy) and establish the preferred dose parameters. Secondary endpoints included: (1) efficacy relating to the time to onset of analgesia and the duration of effect from a single oral dose and (2) safety as measured by the incidence and intensity of opioid-related adverse events.

Of the patients receiving 12mg/8mg dose of morphine/oxycodone, 58% reported good to excellent global improvement (as compared to 13% for placebo) and demonstrated the greatest dose-response effect ( $p < 0.0003$ ) in terms of reducing pain intensity scores as well as other measures of analgesic effect.

Post-surgery and prior to the first 12mg/8mg dose of Q8003IR, the baseline patient pain intensity (PI) scores averaged 6.6 out of 10 units -- with 10 being the most severe on the Numerical Pain Rating Scale. Analgesic effects as reflected in the maximum pain improvement (PI) for the 12mg/8mg dose of Q8003IR yielded a 2 unit reduction of PI (decreasing patient scores to 4.6) versus a 0.14 unit *increase* of PI for placebo-treated patients. Placebo patients were treated with ibuprofen, a non-opioid analgesic.

The mean time to confirmed perceptible pain relief for Q8003IR was 42 minutes compared to 4.4 hours for placebo. The duration time of analgesic effect was 6.6 hours for Q8003IR versus 2.8 hours for placebo.



The 12mg/8mg dose data demonstrated that Q8003IR was well tolerated, with a low rate of patient withdrawal (8% discontinuing use due to adverse events and 6% discontinuing use due to efficacy failure) compared to placebo (with 2% discontinuing use due to adverse events and 25% discontinuing use for efficacy failure). Only 2% of 12mg/8mg Q8003IR treated patients experienced somnolence, and no incidences of euphoria were reported. The low level of somnolence and absence of euphoria reported were unexpected outcomes compared to what is typically seen with morphine or oxycodone. The significance of these observations will need to be confirmed in future studies that provide a direct data comparison.

All patients exhibited acceptable respiratory rates with reduction in blood oxygen levels occurring in less than 2% of those on the preferred dose of Q8003IR. Typical of opioid drugs, nausea and vomiting were the most common adverse events. Of patients receiving the 12mg/8mg dose, 56% experienced mild to moderate nausea that diminished over the first few hours of treatment; no incidences of severe nausea were reported. 32% of patients reported vomiting with initial dosing (18% mild to moderate and 14% severe). 20% of patients experienced mild to moderate dizziness; no incidences of severe dizziness were reported.

Q8003IR is an immediate release dual opioid product candidate intended for the acute management of moderate to severe pain, a \$2.5 billion dollar market in the US alone. This patent-protected combination of morphine and oxycodone has been clinically shown to provide synergistic effects on pain relief with a significant reduction of total opioid dose and side effects. Final Phase 3 studies with Q8003IR will be initiated shortly to complete the required data package for New Drug Application (NDA) submission to the US Food and Drug Administration (FDA) in 2009 as planned.

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### **Forward Looking Statements**

This press release contains forward-looking statements that involve risks and uncertainties. The forward-looking statements contained herein represent the judgment of QRxPharma as of the date of this release. These forward-looking statements are not



guarantees for future performance. Actual results could differ materially from those currently anticipated to due to a number of factors including 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) 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 directly commercialise its products in the US and seek strategic partnerships abroad. QRxPharma's lead compound, Q8003IR, successfully completed a Phase 3 study and met primary and secondary endpoints. 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).