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QRxPharma Releases Successful Phase 3 Study Results for 'Dual Opioid' Pain Therapy

Q8003IR Met Primary Endpoints; Demonstrated Strong Reduction of Pain Intensity

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 initial Phase 3 efficacy results for Q8003IR, an immediate release dual-opioid product intended for the acute management of moderate to severe pain.

“Initial Phase 3 efficacy data demonstrated statistically significant analgesic activity at all doses tested and reinforces the potential clinical benefit and commercial value of QRxPharma’s lead dual-opioid product,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We are pleased with this study outcome and believe that it demonstrates that the Company remains on target to complete clinical testing for Q8003IR, submit a New Drug Application (NDA) in 2009 and achieve its goal of product launch in 2010.”

The double-blind, placebo-controlled study was designed to compare the efficacy and safety of four different dosage regimens of Q8003IR, a fixed ratio morphine/oxycodone combination. 256 patients with moderate to severe pain following surgery (bunionectomy) completed the trial, and it was conducted at six US clinical research sites. The primary efficacy analysis compared the change in pain intensity scores over the 48 hr dosing period (SPID48) in patients receiving Q8003IR vs. placebo.

Among all patients receiving Q8003IR, approximately 50% reported good to excellent global improvement (vs 13% for placebo) and demonstrated a strong dose-response effect ($p < 0.001$) in reducing pain intensity scores [i.e. the sum of pain intensity difference over 48 hours relative to the first dose (SPID48)] and other measures of analgesic effect. Per treatment group, median doses received every 4 hours ranged from 3mg/2 mg to 9mg/6 mg of morphine/oxycodone.

The data further demonstrate that Q8003IR was generally well tolerated, with a low rate of patient withdrawal (2% to 12% depending on dose vs. 2% for placebo). In addition, there was minimal somnolence (2% to 8%) and changes to respiratory parameters (respiration rate, oxygen saturation) with no incidences of euphoria reported. Nausea and vomiting (usually mild) were the most common adverse events. Further analysis of side effect profiles is underway and these data will be available by late May 2008.



Q8003IR is a patent-protected combination of morphine and oxycodone which has been clinically shown to provide synergistic effects on pain relief with a significant reduction of total opioid dose and side effects.

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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 commercialization of the Company's proposed products.

About QRxPharma

QRxPharma (ASX: QRX) is a clinical-stage specialty pharmaceutical company focused on the development and commercialization 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 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.