



**ASX RELEASE**  
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## **QRxPharma Initiates Phase 3 Comparative Safety Study of MoxDuo<sup>®</sup> IR**

*Study Designed to Evaluate Side Effect and Safety Advantages of MoxDuo IR Compared to Equi-Analgesic Doses of Morphine and of Oxycodone*

**Sydney, Australia and Bedminster, New Jersey** - QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today initiation of a Phase 3 trial (Study 022) to compare the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone given alone. Specifically, the study compares the incidence level of the opioid-related adverse events of moderate to severe nausea, vomiting and dizziness and changes in respiratory function in patients with moderate to severe postoperative pain following bunionectomy surgery. The Company expects to complete dosing in Q2 CY2011. The results of the trial will form part of a Marketing Authorisation Application (MAA) filing scheduled for submission later this year for approval to market in Europe. Study results, when published in medical literature, may, in conjunction with other trial data, be a component of the promotional package following projected commercial launch of MoxDuo IR in the US and in Europe in 2012.

“Every trial conducted to date has demonstrated the benefits of MoxDuo, achieving as good or better pain relief with fewer incidences of moderate to severe side effects when compared with morphine, oxycodone or Percocet<sup>®</sup>,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We expect this head-to-head comparison of MoxDuo IR versus equi-analgesic doses of morphine and oxycodone will provide data confirming the competitive advantages of our product over current standards of care.”

Study 022 is a randomised, double-blind and fixed-dose comparison of MoxDuo IR (12 mg morphine/ 8 mg oxycodone) vs. morphine equivalent doses of morphine (24 mg) and oxycodone (16 mg) given once every 6 hours for up to 2 days. It will enrol approximately 375 patients (n=125 per treatment group) at 4 US clinical research sites. At least 40% of the patients will be 60 years of age or older.



Safety will be measured by recording adverse events, changes in vital signs and respiratory function as well as other endpoints. The main efficacy measure is the difference from baseline in pain intensity scores (10 point Numerical Pain Rating Scale) for each treatment group over the 48-hour treatment period [Sum of Pain Intensity Differences over 48 hours (SPID<sub>48</sub>)]. Study results are expected to confirm the significant tolerability and safety advantages of MoxDuo IR.

A prior QRxPharma study (021) in patients experiencing acute postoperative bunionectomy pain demonstrated the potential side effect and safety benefits of a lower dose 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 morphine-equivalent dose (MED). The present Phase 3 study (022) is similarly designed, but compares MoxDuo (12 mg/8 mg) with 24 mg MEDs of morphine and oxycodone where significant side effects are expected.

MoxDuo IR targets the acute pain market, a \$2.5 billion segment of the over \$7 billion spent annually on prescription opioids in the US. In April 2010, the Company released results from a “combination rule” pivotal study (008) comparing the 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. MoxDuo IR not only demonstrated a statistically superior analgesic effect compared to component doses of morphine (p=0.02) and oxycodone (p=0.02) but, also a favourable side effect profile despite delivering twice the opioid dose of its individual components. With this trial, combined with the recently completed total knee replacement study (009 – data to be reported shortly), the Company believes it has met the basic clinical data requirements for NDA filing in Q2 CY2011 as planned.

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