



**ASX RELEASE**  
27 April 2011

## **QRxPharma Completes Patient Enrolment of MoxDuo<sup>®</sup> IR Phase 3 Comparative Safety Study**

*Evaluated Tolerability and Safety Advantages of MoxDuo IR Compared to Equi-Analgesic Doses of Morphine and Oxycodone*

**Sydney, Australia and Bedminster, New Jersey --** QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today it has completed patient enrolment for Study 022, a Phase 3 trial comparing the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone. Specifically, the study evaluated the incidence of opioid-related adverse events – including changes in respiratory function, moderate to severe nausea, vomiting and dizziness – in patients with moderate to severe postoperative pain following bunionectomy surgery. The trial enrolled 375 patients (n=125 per treatment group) at 5 US clinical research sites. QRxPharma expects to release top-line data in June.

“This Phase 3 trial represents a major milestone as it is the first comparison MoxDuo IR (12 mg/8 mg) to equi-analgesic doses of morphine and oxycodone,” said Dr. John Holaday, Managing Director and CEO, QRxPharma. “With patient enrolment complete, we are optimistic that the pending results will confirm the significant tolerability and safety advantages of MoxDuo IR over these two widely prescribed opioids.”

A prior comparator study in patients experiencing acute postoperative bunionectomy pain demonstrated the potential side effect and safety benefits 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 MED (morphine equivalent dose).

This Phase 3 study was similarly designed, but compared MoxDuo IR (12 mg/8 mg – 24 mg MED) with equi-analgesic doses of morphine (24 mg) and oxycodone (16 mg). By design, approximately 40% of the enrolled subjects were age 60 years or older, thus providing ample evaluation of the tolerability of the three treatments in this age group.

Trial results will form part of QRxPharma’s European Marketing Authorisation Application (MAA) scheduled for submission in the first quarter of 2012. Study results, when published in medical literature, may, in conjunction with other trial data, be a component of the promotional package following the projected commercial launch of MoxDuo IR in the US in 2012 and in Europe in 2013.

