



For Immediate Release
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QRxPharma Releases Additional Pivotal Phase 3 Combination Rule Study Data for MoxDuo[®] IR in Patients with Post-Surgical Pain

Data Demonstrate Dual-Opioid[™] Provides Significantly Better Pain Relief Compared to Component Doses; Study Goals and Secondary Endpoints Met


Sydney, Australia and Bedminster, New Jersey – QRxPharma (ASX: QRX and OTCQX: QRXPY) announced today the release of additional pivotal Phase 3 trial data for MoxDuo IR, an immediate-release Dual-Opioid pain therapy. Required for New Drug Application (NDA) submission with the United States Food and Drug Administration (FDA), this “combination rule” study compared 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 statistically superior analgesic effect compared to component doses of morphine ($p=0.01$) and oxycodone ($p=0.01$) but, also, a favourable side effect profile despite delivering twice the opioid dose of its individual components. The trial enrolled 522 patients at 6 US clinical research sites. Primary and secondary endpoints were met.

“While the initial trial data demonstrated the superiority of MoxDuo IR in terms of analgesic effect, further analysis revealed equally important findings in terms of superior overall pain relief, reduced reliance on supplemental analgesia and strong tolerability,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “These findings are consistent with earlier comparative data and reinforce both the clinical benefit and commercial potential of MoxDuo IR – our lead Dual-Opioid product candidate.”

The primary endpoint for evaluating the efficacy of MoxDuo IR 12 mg/8 mg versus its milligram components (morphine 12 mg and oxycodone 8 mg) was the difference in pain intensity scores from baseline for each patient over the 48-hour treatment period (SPID₄₈).

Secondary endpoints included: (1) efficacy relating to the amount of supplemental analgesic (ibuprofen) used throughout the treatment period; (2) difference in pain intensity scores from baseline for each patient over the first 24-hour treatment period (SPID₂₄); and (3) safety as measured by incidence and intensity of opioid-related adverse effects.

In terms of supplemental analgesia, patients in the morphine and oxycodone control groups were 2-3 times more likely to use ibuprofen supplemental dosing than those receiving MoxDuo IR ($p<0.05$ to $p<0.01$). Control groups were also more likely to use ibuprofen in greater amounts and earlier in the treatment period than patients receiving MoxDuo IR ($p<0.01$ to $p<0.001$). Even with



the extra use of rescue medication in the control groups, at both 24 and 48 hours, the amount of pain reduction from baseline was significantly less compared to patients receiving MoxDuo IR ($p < 0.05$ to $p < 0.001$).

The enhanced tolerability of MoxDuo IR seen in earlier studies was further validated in this pivotal Phase 3 combination rule trial. Whilst patients in the MoxDuo IR (12/8mg) arm received twice the morphine equivalent dose of patients in the other two comparator arms (morphine 12 mg or oxycodone 8mg), the incidence and intensity of moderate to severe side effects remains similar whilst efficacy was higher with MoxDuo IR. This tolerability is further evidenced by the 93% to 95% patient completion rate in the study treatment groups.

“By delivering twice the opioid dose, one would expect a substantial increase in both the incidence and intensity of a broad range of side effects, but that is not the case with MoxDuo IR,” added Holaday. “Our Dual-Opioid™ formulation provides improved pain relief and greater tolerability as each drug component acts on different receptors. This means we can enhance analgesia without significantly increasing side effects.”

Among all groups, the most common moderate to severe adverse events were CNS (i.e. dizziness, somnolence, etc.) with an incidence range of 10% to 15%; gastrointestinal (i.e. nausea, emesis, etc.) with an incidence range of 15% to 30%; and dermatological (i.e. itchiness, skin rash, etc.) with an incidence range of 2% to 6%. The percentage of patients in the MoxDuo IR group who reported moderate to severe vomiting was less than seen in previous studies and this was the only side effect that occurred more frequently with MoxDuo IR than its half-dose components.

“Having satisfied the combination rule requirement, we now turn our attention to the second and final MoxDuo IR registration trial, a study to evaluate the effectiveness of MoxDuo IR in patients following total knee replacement surgery, which was initiated in February 2010 and projected to complete dosing in Q3 2010,” said Holaday.


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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 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 for worldwide markets. QRxPharma's lead product candidate, MoxDuo[®]IR, 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. Data collected from these studies provided additional guidance for optimising the design and initiation of two pivotal Phase 3 studies required for New Drug Application (NDA) filings with the US Food and Drug Administration (FDA). QRxPharma expects to complete its Phase 3 program Q3 CY2010 and file its NDA for MoxDuo[®]IR in Q4 CY2010. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit www.qrxpharma.com.