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QRxPharma refiles Moxduo NDA with FDA

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Singapore: Australia-based QRxPharma has resubmitted its Moxduo new drug application (NDA) after the US Food and Drug Administration (FDA) provided QRxPharma with guidance on its requirements for the NDA refiling as well as data validation documentation.

"We are confident that our refiled NDA will confirm the validity of the data defining the product's respiratory safety advantages and we are hopeful that the FDA will view them favourably in their consideration of the benefits of immediate release Moxduo as a therapeutic option for the millions of patients who suffer from acute pain," said Dr John Holaday, MD and CEO, QRxPharma. "We were encouraged by our candid dialogue with the FDA throughout this process, and will continue to liaise closely with the Agency to bring Moxduo to market."

The FDA previously confirmed that the company's Combination Rule Trial, Study 008, satisfied efficacy requirements and that there were no efficacy or safety issues identified in any of the studies submitted in the original NDA.

Dr Holaday said, "QRxPharma completed an audit of the more than 30 million data points for oxygen desaturation from Study 022. We believe these data demonstrate a significant respiratory safety advantage for Moxduo over equi-analgesic doses of morphine or oxycodone. Furthermore, Moxduo provides a lower starting dose and finer dose titration steps than acute pain opioids presently available, giving greater flexibility to physicians and patients as the need for pain relief is balanced with lower risks of side effects."

"We expect the FDA to schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following this submission, projected for late May, 2014. We will keep our shareholders informed as we receive feedback from the FDA, and assuming approval, we anticipate product launch with our US commercialization partner, Actavis, in the second half of CY2014," added Dr Holaday.

The revised NDA is the basis for recommencing the regulatory approval for Moxduo for the treatment of moderate to severe pain, a $2.5 billion segment of the USD8 billion spent annually on prescription opioids in the US.