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QRx Pharma gets FDA inputs on Moxduo

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Singapore: Australia-based QRxPharma is proceeding with US FDA to discuss the company's Moxduo new drug application (NDA) and has got complete understanding of the requirements for submission of the revised NDA and data validation documentation.

The FDA reaffirmed that the safety and efficacy of Moxduo are not at question, and that the company's presentation of the totality of the respiratory safety advantages to an advisory committee of experts would help guide their final decision.

Accordingly, the FDA encouraged QRxPharma to submit its validated data and updated NDA. The agency will then schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following NDA resubmission.

"The tone of the meeting with the FDA was cordial and constructive, providing clear recommendations on how we should revise our NDA and document our validated data from the respiratory safety Study 022," said Dr John Holaday, MD and CEO, QRxPharma. "We are highly confident in the integrity of the data defining the respiratory safety advantages of Moxduo, and are now completing the documents for refiling by mid-November 2013."

The revised NDA is the basis for recommencing the regulatory approval process for Moxduo for the treatment of moderate to severe acute pain, a $2.5 billion segment of the $8 billion spent annually on prescription opioids in the US. The revized NDA also serves as the regulatory foundation for submitting Moxduo for approval in Europe, Australia, Canada and other markets in the upcoming months. Assuming approval, the company anticipates that Moxduo will be launched in the US during 2014.