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QRxPharma pain killer's NDA gets FDA response

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Singapore: QRxPharma received complete response letter (CRL) regarding the company's Moxduo new drug application (NDA) from the US FDA for the treatment of moderate-to-severe acute pain.

The company confirmed that the issuance of the CRL was to allow time in order to submit and evaluate further information required for the FDA to fully consider the respiratory safety advantages of Moxduo from study 022.

Following the issuance of the CRL, the company is required to resubmit its NDA in order to maintain FDA review. QRxPharma plans to complete its refiling in Q4 2013, inclusive of the additional information and analysis as requested by the FDA.

QRxPharma anticipates a new Prescription Drug User Fee Act (PDUFA) date in Q2 2014, preceded by an advisory committee meeting. The firm will also have an end of review meeting with the FDA in the coming weeks.

Dr John Holaday, MD and CEO, QRxPharma, said that, "The importance of these documents and their impact on the approval process in terms of accuracy of data, clarity of clinical benefit and comprehensiveness of response, cannot be overstated. In our market update of June 26, we announced timing misalignments in our oxygen desaturation data as the reason for the advisory committee meeting delay. At that time, the duration of the delay was not clear. We now have clarity from the FDA as to next steps, and a six month clock will begin upon refiling the NDA."