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QRxPharma, FDA clarify steps for Moxduo release

17 January 2013 | News | By BioSpectrum Bureau

Singapore: QRxPharma has clarified with the US FDA about the steps necessary for approval of immediate release Moxduo. QRxPharma will resubmit its NDA this quarter, with an expected new PDUFA date to be set for Q3 of 2013.

During the company's most recent FDA review meeting, QRxPharma presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for Moxduo compared to either morphine or oxycodone alone.

Results from Study 022, which demonstrated that oxygen desaturation was less severe with Moxduo than with oxycodone or morphine, were presented to the full review committee and noted with interest. The FDA recommended the company provide a more extensive analysis of Study 022 when the revised Moxduo NDA is resubmitted.

"Throughout the last several years of FDA interactions on Moxduo, we have followed the Agency's recommendations in designing and implementing clinical trials that demonstrated its effectiveness and safety in acute pain patients," said Dr John

Holaday , managing director and chief executive officer, QRxPharma. "Recent feedback provided clarity as to the complete response action taken on June 25, 2012, and based on the FDA's advice and recommendations, we are now preparing our revised NDA for submission this quarter."

"While US approval of Moxduo remains our foremost priority and we are optimistic about next steps with the FDA, we also look forward to submitting regulatory filings in Canada, Europe and Australia before the end of the fiscal year that will further support the Company's strategies for commercialising the product around the world," concluded Dr Holaday.