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QRxPharma resubmits Moxduo NDA to US FDA

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Singapore: QRxPharma announced that the company resubmitted its Moxduo New Drug Application (NDA) to the US FDA. As disclosed on January 16, 2013, at its last meeting with the company, the FDA requested the resubmission of the NDA to include the respiratory safety results of Study 022.

"We believe the revised documents effectively address the FDA's request for additional data resulting from their review of the initial Moxduo NDA filed in mid-2011," said Dr John Holaday, managing director and chief executive officer, QRxPharma. "To this end, and as recommended by the FDA, a comprehensive analysis of Study 022 was included as part of the resubmitted NDA. This study demonstrated the lower risks of respiratory depression for Moxduo when compared to either morphine or oxycodone."

QRxPharma believes the resubmitted clinical data demonstrate safety advantages of Moxduo over its components, morphine and oxycodone, and that Moxduo provides as good or better analgesia as indicated by past studies involving more than 1,600 patients experiencing moderate-to-severe acute post-operative pain.

The primary safety advantage of Moxduo over its components is a reduction in respiratory risks evident in the data from Study 022. Furthermore, cross study analyses of all patients in the NDA programme demonstrate that Moxduo is associated with less vomiting and a lower incidence of other side effects than comparable analgesic doses of morphine or oxycodone. Moxduo also provides a safer starting dose and finer dose titration steps than either of its components, thus giving greater flexibility to physicians and patients as the need for pain relief is balanced with the lower risks of side effects.

"In addition to the results of Study 022, this revised NDA includes the results of five other Phase 2 and 3 clinical trials conducted by the Company over the past six years showing less nausea, vomiting, itching and headache in patients treated with Moxduo," added Dr Holaday.

The FDA confirmed that there were no efficacy or safety issues in any of the studies that were part of the original NDA. The resubmitted application, including new results from Study 022, will undergo review by an Advisory Committee to evaluate the approvability of Moxduo in the management of acute pain. By the end of this quarter, the Company expects to be notified of the new Prescription Drug User Fee Act (PDUFA) date for action by the FDA, as well as the date for the Advisory Committee

meeting.

"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, before the end of this calendar year," concluded Dr Holaday.