DORYX® GENERIC UPDATE

10 February 2011, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) announces that the US Food and Drug Administration (FDA) has granted final approval of Mylan Pharmaceuticals Inc.'s (Mylan) generic single-scored 150mg doxycycline hyclate delayed-release tablet, with a post approval requirement to comply with the new dual scoring configuration of the reference listed drug product when it conducts its next manufacturing run.

Mayne Pharma's CEO Dr Roger Aston said, "Although we are surprised by the FDA's decision to approve Mylan's generic product, we are currently in the middle of the trial reviewing the Doryx® '161 Patent. The FDA's decision is made independent of the patent hearing and the Court has issued a temporary restraining order preventing the launch of Mylan's generic product until the Court issues a decision on the case."

On 1 February 2012, the Doryx® patent trial began in the US District Court of New Jersey. The defendants in the hearing are Mylan and Impax Laboratories Inc. as three other paragraph IV companies, Heritage Pharamceuticals Inc, Actavis Elizabeth LLC and Sandoz Inc have settled with Mayne Pharma and Warner Chilcott under terms that allow generic equivalents to enter the market on or after December 15, 2016, subject to certain exceptions and conditions.

A decision by the Court is expected by late February or early March 2012. In the event that the US District Court decides against Mayne Pharma and Warner Chilcott, both Companies intend to pursue their legal rights including possible appeal of such a decision.

-ENDS-

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