



MAYNE PHARMA ANNOUNCES FDA APPROVAL OF NEW DUAL-SCORED 150MG DORYX® TABLET

14 September 2011, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that the US Food and Drug Administration (FDA) has approved a dual-scored 150mg Doryx® (doxycycline hyclate) Delayed-Release Tablet. Warner Chilcott, the Company's marketing and distribution partner for Doryx® in the US is expected to begin launch of the product immediately.

Doryx® Delayed-Release Tablets are a tetracycline-class oral antibiotic that contain specially coated pellets of doxycycline hyclate designed to delay the release of doxycycline hyclate until the pellets reach the small intestine, thereby minimising the gastrointestinal side effects most commonly associated with other doxycycline products. The approval and introduction of the dual-scored 150mg tablet to the existing Doryx® franchise offers greater dosing flexibility for patients with the option to break the tablet into 50mg and 100mg doses.

Mayne Pharma's CEO, Dr Roger Aston, said "We are pleased to have been granted approval of the dual-scored 150mg Doryx® tablet which reinforces Mayne Pharma's commitment to provide greater flexibility and treatment options for patients and to continue its strategy to lifecycle manage Doryx® into new dose strengths and formulations."

The FDA's policy on the scoring¹ configuration of tablets generally stipulates that if a reference-listed drug adds a score to a tablet, the generic product should follow the same scoring configuration. Accordingly, it is Mayne Pharma's expectation that the FDA is likely to ask companies with a single score 150mg generic tablet to develop and gain approval for a dual-scored 150mg generic tablet prior to launch.

Mayne Pharma is the owner of a granted US patent covering the Doryx® formulation which expires in 2022 and together with its partner Warner Chilcott continues to vigorously defend its Doryx® patent and take legal action against any companies seeking to infringe the patent with generic products.

-ENDS-

¹ Scores are lines in tablets running across the surface enabling a tablet to be broken into fractions when less than the full tablet is required for a dose.

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Mayne Pharma Profile:

Mayne Pharma Group Limited (Mayne Pharma) is an Australian specialist pharmaceutical company with an intellectual property portfolio built around the optimisation and delivery of oral dosage form drugs.

Mayne Pharma has a long and successful history of developing and commercializing improved pharmaceuticals and has launched and marketed numerous products through partnerships with licensees in various countries around the world. Mayne Pharma focuses on delivering to patients improved versions of existing drugs in order to advance safety, efficacy or ease of administration.

A technology driven company, Mayne Pharma has a significant product portfolio and pipeline, global reach through distribution partners in Australia, USA, Europe and Asia and a manufacturing facility based in Salisbury, South Australia that employs over 130 people on a 32 acre site. The facility also undertakes the manufacture of products under contract for third parties to TGA, FDA and EU regulatory guidelines.