MAYNE PHARMA ANNOUNCES DECISION ON APPEAL OF DORYX® PRELIMINARY INJUNCTION

13 December 2011, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) announces that the U.S. Court of Appeals for the Federal Circuit vacated a preliminary injunction granted by the U.S. District Court for the District of New Jersey against Mylan Inc. and its affiliate Mylan Pharmaceuticals Inc. (together "Mylan") and remanded the matter back to the District Court for further proceedings. In vacating the District Court's September 2011 preliminary injunction that prohibited Mylan from launching a generic version of a Doryx® 150 mg product before a decision at trial, the Federal Circuit found that the District Court failed to hold an evidentiary hearing and to make sufficient findings with respect to Mylan's invalidity defenses.

Mayne Pharma and Warner Chilcott intend to continue to vigorously defend the '161 Patent and pursue their legal rights in their pending suits against Mylan and the other defendants that have submitted ANDAs to the FDA seeking approval to manufacture and sell generic versions of a Doryx® 150 mg product. More specifically, Mayne Pharma and Warner Chilcott expect to seek a rehearing of today's decision at the Federal Circuit and, if necessary, seek a temporary restraining order from the District Court to allow for the consolidation of the preliminary injunction hearing with the trial on the merits of the '161 Patent. The trial is currently expected to occur in the first quarter of 2012.

Mayne Pharma manufactures and supplies Doryx®, a tetracycline-class oral antibiotic to Warner Chilcott in the United States under a license agreement and owns the '161 Patent. As previously disclosed, in September 2011 the FDA approved a dual-scored Doryx® 150 mg product. The Company has also filed a citizen petition requesting that the FDA refrain from granting final approval of any Doryx® abbreviated new drug application ("ANDA") seeking to manufacture and sell generic versions of a Doryx® 150 mg product, unless the ANDA filer's product also adopts a dual-scored configuration and has the same labelling as the Company's dual-scored Doryx® 150 mg product. The FDA is yet to formally respond to the citizen petition.

In the event that the Federal Circuit denies Mayne Pharma and Warner Chilcott's motion for rehearing, the District Court denies Mayne Pharma and Warner Chilcott's motion for a temporary restraining order, and Mylan receives final FDA approval of its generic version of a Doryx® 150 mg product, Mylan could elect to launch its product "at risk" before the District Court renders a decision in the ongoing litigation relating to the '161 Patent. The Company can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful, whether the FDA will grant its citizen petition request, or whether generic equivalents of a Doryx® 150 mg product will be approved and enter the market prior to the expiration of the '161 Patent in 2022.

-ENDS-

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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 150 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.