



## ANNOUNCEMENT

### **MAYNE PHARMA ANNOUNCES SUBMISSION OF MARKETING AUTHORISATION APPLICATION FOR SUBACAP™**

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**17<sup>th</sup> December 2010, Melbourne Australia:** Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that it has submitted a Marketing Authorisation Application (MAA) in the European Union (EU) for SUBACAP™, an improved version of an existing drug (itraconazole) to treat fungal infections. The marketing of SUBACAP will initially target the global US\$600M plus itraconazole market.

The MAA has been submitted via the Decentralised Procedure, with the United Kingdom as the Reference Member State and France, Germany, Spain and Sweden as the Concerned Member States.

The approval timeline will be subject to the regulatory authority review process and is anticipated to take approximately 9-12 months. Mayne Pharma is expecting to receive income from the first market sales of SUBACAP™ in calendar 2012 subject to the appointment of a marketing and distribution partner.

Mayne Pharma's CEO, Dr Roger Aston said "This is a significant milestone for the company. Mayne Pharma joins a select group of Australian Companies to have filed a dossier for the registration of a new drug formulation in recent years."

"This is a great result as the EU market for itraconazole is estimated at over US\$120 million, being greater than that for the US. The global itraconazole market is in excess of US\$600 million and by achieving early EU registration, the approved dossier may be used for faster approval in Asian and South American countries."

"Over the next few months, we will be focused on establishing suitable commercial relationships for the marketing and distribution of SUBACAP™ in Europe and elsewhere. We will also be meeting with the FDA in early 2011 to receive guidance on further requirements for US registration, following our successful Phase II trial that demonstrated SUBACAP™ will offer a safe low-dose replacement to Sporanox®, a current leading treatment for fungal infections."

**-ENDS-**

**For Further information contact:**

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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.