

## MAYNE PHARMA ANNOUNCES US PARAGRAPH IV CHALLENGE

- US\$150 million Tikosyn® brand
- Eligible for 180 days exclusivity
- Granted priority review by US FDA

**18 November 2014, Melbourne Australia:** Mayne Pharma Group Limited (ASX: MYX) today confirmed that one of its US-based subsidiaries has been sued by Pfizer Inc., in connection with the filing of an Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA) for Dofetilide capsule in the 0.125mg, 0.25mg, 0.5mg strengths. The ANDA product is a generic version of Pfizer's Tikosyn® which is an antiarrhythmic agent to prevent irregular heartbeats such as atrial fibrillation and atrial flutter.

Based on available information, Mayne Pharma believes its US-based subsidiary may be the "first applicant" to file an ANDA for the generic version of Tikosyn® and, should its ANDA be approved, it may be entitled to 180 days of generic market exclusivity. For the 12 months ending 30 September 2014, Tikosyn® had total US sales of approximately \$150 million, according to IMS Health.

Pfizer filed suit against one of Mayne Pharma's US-based subsidiaries in the US District Court for the Eastern District of Virginia and Southern District for New York seeking to prevent it from commercialising its ANDA product prior to the expiration of the US Patent 6,124,363. The lawsuit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of the ANDA for up to 30 months from the date the plaintiffs received notice of the ANDA filing or until resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivities. The FDA has also granted priority review for this ANDA.

Mayne Pharma has entered into an agreement with a development partner to share equally the litigation costs and potential profits from the sale of the product.

Mayne Pharma has 17 products pending FDA approval representing approximately US\$1.8 billion in annual sales according to IMS Health.

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## ASX Announcement

### About Mayne Pharma

*Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes globally; either directly or through distribution partners and also provides contract development and manufacturing services.*

*Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.*

*Mayne Pharma has two drug development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.*

Tikosyn® is a registered trademark of Pfizer Inc.