

## PFIZER WITHDRAWS US TIKOSYN® LITIGATION AGAINST MAYNE PHARMA

- Significant first-to-file opportunity for US generic business
- Eligible for 180-days exclusivity
- US\$150m Tikosyn® brand

25 February 2015, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) today announced that it has reached an agreement with Pfizer Inc. to end litigation with regard to the Company's generic version of Tikosyn® (Dofetilide capsules, 0.125mg, 0.25mg and 0.5mg). Tikoysn® is an antiarrhythmic agent to prevent irregular heartbeats such as atrial fibrillation and atrial flutter. According to IMS Health, annual sales of Tikosyn® in the US were approximately US\$150 million for the twelve months ended 31 December 2014.

Pfizer has withdrawn its legal action against Mayne Pharma, enabling the Company to enter the US market with a generic version of Tikosyn® following approval by the US Food and Drug Administration (FDA). Mayne Pharma's abbreviated new drug application (ANDA) for generic Tikosyn® is currently under a priority review with the FDA.

Mayne Pharma's CEO, Mr Scott Richards said, "Our expeditious resolution of the patent litigation with Pfizer on what we expect is a First-to-File ANDA for Tikosyn® is a significant event for our US generics business. This agreement allows Mayne Pharma to bring a generic version of Tikosyn® to the US market prior to the October 2018 expiration of Pfizer's patent, without incurring the uncertainty, cost and risk inherent with patent litigation. Furthermore, we expect to be awarded a 180-day exclusivity period upon approval which we anticipate as early as 2016."

Mayne Pharma has an agreement with Johnson Matthey Inc., the active pharmaceutical ingredient supplier, to share equally the potential profits from the sale of this product.

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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.