

MAYNE PHARMA RECEIVES FDA APPROVAL FOR DOFETILIDE CAPSULES AND AWARDED 180-DAYS MARKET EXCLUSIVITY

- First generic approval to Pfizer's US\$200m Tikosyn® brand
 - Awarded 180-days of market exclusivity as the first company to file a substantially complete ANDA containing a Paragraph IV certification
 - Commercial launch has commenced
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7 June 2016, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that the US Food and Drug Administration (FDA) has granted approval of its Abbreviated New Drug Application (ANDA) for dofetilide capsules (125 mcg, 250mcg and 500 mcg) in the United States.

Mayne Pharma was the first company to file a substantially complete ANDA containing a Paragraph IV certification for dofetilide capsules and as a result has been awarded 180-days of market exclusivity. Mayne Pharma has immediately commenced commercial launch.

Dofetilide capsules are a generic version of Pfizer's Tikosyn® capsules, an anti-arrhythmic agent used 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\$200 million for the twelve months ended April 2016.

Mayne Pharma's CEO, Mr Scott Richards, said "We are proud to be the first generic alternative to Tikosyn® in the US, bringing significant cost savings to patients requiring this life-saving drug. As the Company's first generic product to receive 180-days of market exclusivity, the approval and launch of dofetilide is a significant milestone for our Company. Today's approval accelerates our growth and underscores our investment and commitment to bringing complex generic products to the marketplace."

The timing of Mayne Pharma's market approval coincided with the FDA withdrawing the Tikosyn® Risk Evaluation and Mitigation Strategies (REMS) program, which limited the drug's availability and dispensation to certified prescribers, pharmacies and wholesalers. The removal of the drug's REMS program means that Mayne Pharma's dofetilide capsules can be more readily stocked by pharmacies nationwide — improving availability for current and new patients.

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



ASX Announcement

Currently, Mayne Pharma has more than 35 generic and branded drug products in development targeting US markets with IMS sales greater than US\$6.5 billion. Mayne Pharma expects further product launches over the coming year with 12 drug applications pending at the FDA.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

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 product 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.