ASX Announcement

MAYNE PHARMA ANNOUNCES FDA APPROVAL AND IMMEDIATE LAUNCH OF DOXYCYLINE HYCLATE IR TABLETS, FIRST GENERIC TO ACTICLATE®

15 Jun 2017, 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 doxycycline hyclate immediate release (IR) tablets (75 mg and 150 mg) in the United States. Mayne Pharma has immediately commenced commercial launch to customers in the US.

Doxycycline hyclate IR tablets are a generic version of Acticlate® tablets, a tetracycline-class antibacterial indicated for the treatment of a number of infections, including adjunctive therapy in severe acne. According to IMS Health, annual sales of Acticlate® in the US were approximately US$250 million for the twelve months ended April 2017.

Mayne Pharma's CEO, Mr Scott Richards, said "We are very pleased to have launched the first generic alternative to Acticlate® in the US, providing more choices to patients and payers in terms of medication affordability. Today's approval exemplifies Mayne Pharma's commitment to bringing first-to-market generic products to the marketplace."

The launch of doxycycline hyclate IR tablets is Mayne Pharma's fourth first-to-market generic launch since June last year after dofetilide capsules, butalbital acetaminophen tablets (50 mg/300 mg) and methylphenidate extended-release capsules (60 mg).

Mayne Pharma markets more than 50 products and has a growing pipeline of more than 40 products targeting US markets with IMS sales greater than US$7 billion. With 18 drug applications pending at the FDA, Mayne Pharma anticipates additional product launches within the coming year.

For further information contact:
Scott Richards +61 8 8209 2410
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

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.

Acticlate® is a registered trademark of Aqua Pharmaceuticals LLC.