ASX Announcement

MAYNE PHARMA'S GENERIC NUVARING® ANDA ACCEPTED FOR FILING BY FDA

20 March 2018, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce its Abbreviated New Drug Application (ANDA) for generic NuvaRing® has been accepted for filing by the US Food and Drug Administration (FDA).

NuvaRing is an intra vaginal hormonal contraceptive delivery device combining etonogestrel and ethinyl estradiol over a 3-week period. Merck's NuvaRing had total US sales of approximately US$830 million for the 12 months ending 31 January 2018, according to IQVIA.

Mayne Pharma's CEO Scott Richards said, "We are very pleased to have received filing acceptance for our generic NuvaRing, which is an important regulatory milestone. Generic NuvaRing is a complex and difficult-to-develop and manufacture product and complements our existing women's health franchise of 21 marketed products. Following the Teva portfolio acquisition, Mayne Pharma became the second largest supplier of oral contraceptives in the US. NuvaRing is the largest contraceptive sold in the US$5.6 billion US contraceptive market with no generic equivalents today. We currently expect to commercialise our generic NuvaRing in FY19."

In February 2017, the Company entered into a long-term exclusive license and supply agreement with Mithra Pharmaceuticals, SA (Mithra), a leading women's health drug delivery company. Under the terms of the agreement, Mayne Pharma will have responsibility to market, sell and distribute the product following FDA approval and Mithra will be responsible for supply.

Mayne Pharma directly markets more than 55 products and has a growing pipeline of approximately 30 products targeting US markets with IQVIA sales greater than US$5 billion.

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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.

About Generic NuvaRing

Generic Nuvaring (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, combination contraceptive vaginal ring, with an outer diameter of 54 mm and a cross-sectional diameter of 4 mm. It is made of ethylene vinylacetate copolymers, and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol. When placed in the vagina, each ring releases, in line with the originator (NuvaRing), on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. The ring is to remain in place continuously for three weeks. It is removed for a one-week break, during which a withdrawal bleed usually occurs. A new ring is inserted one week after the last ring was removed.

The originator (NuvaRing) is protected in the US by an Orange Book listed patent that expires in April 2018.

NuvaRing® is a registered trademark of N.V. Organon Corporation