



MAYNE PHARMA EXECUTES LICENSE AND SUPPLY AGREEMENT FOR GENERIC NUVARING® IN THE US

28 February 2017, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has entered into a long-term exclusive license and supply agreement with Mithra Pharmaceuticals, SA (Mithra) for Myring®, an intra vaginal hormonal contraceptive delivery device. Under the terms of the agreement, Mayne Pharma will have responsibility to market, sell and distribute the product following US Food and Drug Administration (FDA) approval and Mithra will be responsible for supply.

Myring is a non-biocompatible, flexible ring shape device combining etonogestrel and ethinyl estradiol over a 3-week period. It is currently under development by Mithra, a specialty pharmaceutical company focused on the development, manufacturing and commercialisation of innovative and differentiated drugs and therapeutic solutions in women's health. Mithra has completed bioequivalence studies and Mayne Pharma expects to file this product with the FDA in 2017.

Myring has been developed to be an AB-rated generic to Merck's NuvaRing® which had total US sales of approximately US\$780 million for the 12 months ending 31 December 2016, according to IMS Health.

Mayne Pharma's CEO, Mr Scott Richards, said "We are very pleased to have licensed Myring which is another complex and difficult-to-develop and manufacture product. Myring complements our existing women's health franchise of 22 hormonal marketed products and four pipeline products. Following the Teva portfolio acquisition, Mayne Pharma became the second largest supplier of oral contraceptives in the US market and we have been actively seeking complementary portfolio and pipeline product opportunities. Nuvaring® is currently the largest product sold in the US\$5.5 billion United States contraceptive market. We are also very excited to be partnering with Mithra a leading women's health drug delivery company."

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ASX Announcement

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, providing patients with access to better and more affordable medicines. 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 the formulation of complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds.

About Myring

Myring is developed to be a generic of Nuvaring® vaginal ring, protected in the US by an Orange Book listed patent that expires in April 2018. Myring (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.

About Mithra

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. dr. Jean-Michel Foidart, is a pharmaceutical company focused on Women's Health. Mithra's mission is to support and assist women at every stage of their life, thereby improving their overall quality of life. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical entities in four therapeutic fields of women's health, fertility and contraception, menopause and osteoporosis, vaginal infections and cancers. Further information can be found at: www.mithra.com.

*Myring® is a registered trademark of Mithra Pharmaceuticals societe anonyme (sa)
Nuvaring® is a registered trademark of N.V. Organon Corporation*

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptives (CHCs) use. The risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, CHC, including NuvaRing, should not be used by women who are over 35 years of age and smoke.

Full prescribing information, including warnings, can be found [here](#).

To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1-844-825-8500 or maynepharmamc@dlss.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.