



MAYNE PHARMA LAUNCHES MICROGESTIN® 24 FE TABLETS IN THE UNITED STATES

7 January 2021, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the commercial launch of MICROGESTIN® 24 FE (norethindrone acetate and ethinyl estradiol tablets, USP, and ferrous fumarate tablets, 1 mg/20 mcg) to customers in the US.

MICROGESTIN 24 FE tablets are a generic version of LOESTRIN® 24 FE tablets indicated for the prevention of pregnancy. According to IQVIA, the annual US market sales of the generic equivalents were approximately US\$75 million for the twelve months ended October 2020.

Mayne Pharma's CEO Scott Richards said, "We are very pleased to launch MICROGESTIN 24 FE which complements our existing women's health portfolio of branded generic contraceptives. As one of the leading suppliers of oral contraceptives in the US, we continue to focus on expanding our portfolio with novel and generic products. Mayne Pharma expects to launch up to seven new contraceptive products over the coming year including the novel oral contraceptive NEXTSTELLIS™ (E4/DRSP), a generic version of NUVARING® and a further five generic products.

"Mayne Pharma's women's health portfolio includes 27 marketed and pipeline products which cover more than 85% of US oral contraceptive prescription volumes¹. MICROGESTIN 24 FE is the first of five anticipated new product launches sourced from the recently announced strategic partnership with Novast Laboratories."

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Authorised for release to the ASX by the Chairman

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, offering patients better and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 40-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 continue to be marketed around the world.

¹ IQVIA MAT Sales and NSP Units for the brand and generic equivalents, October 2020



Mayne Pharma has two facilities based in Salisbury, Australia and Greenville, USA with expertise in the formulation of complex oral and topical dose forms including potent compounds, modified-release products and poorly soluble compounds.

LOESTRIN® is a registered trademark of Allergan Pharmaceuticals International Limited.

Important information

This announcement contains forward-looking statements that involve subjective judgement and analysis and are subject to significant uncertainties, risks and contingencies, many of which are outside the control of, and are unknown to the Company. These forward looking statements use words such as 'potential', 'expect', 'anticipate', 'intend', 'plan' and 'may', and other words of similar meaning. No representation, warranty or assurance (express or implied) is given or made in relation to any forward looking statement by any person (including the Company). Actual future events may vary materially from the forward looking statements and the assumptions on which the forward looking statements are based. Given these uncertainties, readers are cautioned not to place undue reliance on such forward looking statements. Subject to the Company's continuous disclosure obligations at law and under the listing rules of the Australian Securities Exchange, the Company disclaims any obligation to update or revise any forward looking statements. The factors that may affect the Company's future performance include, among others: changes in economic conditions; changes in applicable legal and regulatory regimes that affect manufacturing, distribution, pricing, reimbursement, access or tax; litigation or government investigations; decisions by regulatory authorities including approval of our products as well as their decisions on label claims; competitive developments affecting our products; changes in behaviour of major customers, suppliers and competitors; interruptions to manufacturing or distribution; acquisitions and divestitures; the success of research and development activities and research collaborations.

Select prescribing Information

MICROGESTIN 24 FE is indicated for use by women to prevent pregnancy.

Cigarette smoking increases the risk of serious cardiovascular side effects from combination oral contraceptive (COC) use. This risk increases with age, particularly in over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.

Oral contraceptives should not be used in women who currently have the following conditions: thrombophlebitis or thromboembolic disorders; a past history of deep vein thrombophlebitis or thromboembolic disorders; cerebrovascular or coronary artery disease; known or suspected carcinoma of the breast; carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia; undiagnosed abnormal genital bleeding; cholestatic jaundice of pregnancy or jaundice with prior pill use; hepatic adenomas or carcinomas; and known or suspected pregnancy.

Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

For complete prescribing information and important safety information please visit [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 FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.