

## MAYNE PHARMA SUBMITS NEW DRUG APPLICATION FOR E4/DRSP TO THE FDA

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**16 April 2020, Adelaide Australia and Liege, Belgium** - Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals SA (Euronext Brussels: MITRA) today announced that Mayne Pharma has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA), seeking marketing authorisation for E4/DRSP, a combined oral contraceptive indicated for the prevention of pregnancy in women. If approved by the FDA, E4/DRSP is expected to be made available to patients in the US market in the first half of calendar 2021.

E4/DRSP is a novel, next generation oral contraceptive containing Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg. E4 is a naturally occurring estrogen that is produced by the human foetal liver during pregnancy. Following more than 20 years of research and development, Mayne Pharma's development and manufacturing partner Mithra can synthesise E4 at scale through a complex plant-based production process.

US sales of combined hormonal contraceptives are more than US\$4 billion per annum, according to IQVIA with 10 million American women using combination (estrogen + progestin) oral pills, patches or vaginal rings each day<sup>1</sup>.

**Mitchell Creinin, Professor and Director of Family Planning at the University of California, Davis said,** *"I am excited to see the overall results for E4/DRSP from two phase 3 clinical studies including more than 4,400 women around the world that demonstrated very positive outcomes for efficacy and safety in a product that achieved a desirable bleeding profile and excellent tolerability."*

**Mayne Pharma's CEO Scott Richards said,** *"The NDA filing is a major milestone for Mayne Pharma and our development partner Mithra. We are now one step closer to making this new oral contraceptive that we believe to be safe, effective and well-tolerated available to American women. We confirm our earlier stated goal of bringing this product to market in the first half of calendar 2021."*

**Mithra's CEO Francois Fornieri said,** *"We are very proud of this key milestone for the commercialization of our first blockbuster candidate in the world's largest pharmaceutical market. E4/DRSP is now filed in the US and Europe and we are actively working with our partners for the commercial launch of this product around the world. E4/DRSP promises to provide women with a new choice in oral contraception, in a space where there hasn't been any new innovative hormones introduced for many decades."*

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<sup>1</sup> IQVIA, MAT Sales and NSP Units Feb 2020

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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, 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.*

*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.*

**Mayne Pharma Group Limited**

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**About Mithra**

*Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause.*

*Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): E4/DRSP, a new era in oral contraception, PeriNesta®, the first complete oral treatment for perimenopause and Donesta®, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO.*

*Active in more than 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium.*

**Mithra Pharmaceuticals**

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## **Important information**

*The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.*