



## MAYNE PHARMA EXECUTES 20 YEAR LICENSE AND SUPPLY AGREEMENT FOR NOVEL ORAL CONTRACEPTIVE IN AUSTRALIA

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**28 May 2020, Adelaide Australia:** Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has entered into an exclusive long-term license and supply agreement with Mithra Pharmaceuticals SA (Mithra) to commercialise E4/DRSP, a combined oral contraceptive, in Australia.

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.

The product is expected to be filed with the Therapeutic Goods Administration (TGA) in 2020 with potential launch in the second half of calendar 2021. On approval, the product is expected to receive five years of data exclusivity from the TGA as it is a new chemical entity. Additionally, Mayne Pharma has the option to obtain a license to register and launch E4/DRSP in New Zealand.

Mayne Pharma's CEO Scott Richards said, "We are very pleased to have extended our license for E4/DRSP, an innovative oral contraceptive, for the Australian market. E4/DRSP has a unique mode of action that has shown promising results in two phase 3 clinical studies conducted in 4,400 women with positive outcomes in efficacy and safety and also showed good bleeding profile, cycle control and tolerability."

"This is the third transaction we have completed with Mithra who is also our partner for generic NUVARING® and E4/DRSP oral contraceptive in the US market. We look forward to working closely with the Mithra team on the commercialisation of these key pipeline products over the next 18 months as well as exploring further opportunities to deepen our relationship in the women's health therapeutic category."

The Australian contraceptive market is valued at A\$130m according to IQVIA with the short acting combined (estrogen + progestin) hormonal oral contraceptives estimated at A\$70m with approximately 14m units sold annually<sup>1</sup>.

Mithra's CEO, Mr Francois Fornieri said, "We are delighted to have further strengthened our strategic relationship with Mayne Pharma to now bring E4/DRSP to the Australian market. Mayne Pharma has extensive commercial capabilities and infrastructure to support the launch in Australia and will be able to leverage from launching the product in the US, the world's largest pharmaceutical market, which is targeted for the first half of calendar 2021."

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<sup>1</sup> IQVIA, MAT Sales and units, Dec 2019. A single unit is equivalent to one 28-day cycle.



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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.*

*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 Australia in-licenses pharmaceutical products from international partners in a number of therapeutic areas including women's health such as MONUROL® (fosfomycin trometamol) for the treatment of acute urinary tract infections in females.*

**About Mithra**

*Mithra (Euronext: MITRA) with a market capitalisation exceeding €1 billion is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive E4/DRSP, the first complete oral treatment for perimenopause PERINESTA™ and next-generation hormone therapy DONESTA™ - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO. Mithra was founded in 1999 as a spin-off from the University of Liège by François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at [www.mithra.com](http://www.mithra.com).*

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