



MAYNE PHARMA SIGNS 20 YEAR EXCLUSIVE LICENSE AND SUPPLY AGREEMENT FOR NOVEL ORAL CONTRACEPTIVE IN THE US

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- Mayne Pharma Group Limited (Mayne Pharma or Company) (ASX: MYX) has signed a 20-year exclusive supply and license agreement with Mithra Pharmaceuticals, SA (Mithra) to commercialise a novel oral contraceptive comprising Estetrol (E4), and drospirenone, (E4/DRSP) in the United States
 - Phase 3 clinical studies which enrolled more than 3,700 women have been completed. Approval and launch expected first half of calendar 2021
 - US contraceptive market is valued at US\$5.4 billion with 10 million American women using short-acting combined hormonal contraceptives
 - Expected to be EBITDA positive in its first full financial year following approval
 - Peak net sales potential to exceed US\$200 million per annum
 - Significantly leverages Mayne Pharma's existing leadership position in the US branded generic oral contraceptive market and enhances the potential of pipeline assets such as generic NUVARING®
 - Consideration paid will include a mix of upfront equity and cash along with further equity and cash at FDA approval, together with sales-based milestone cash payments
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Mayne Pharma is pleased to announce it has entered into an exclusive license and supply agreement with Mithra to commercialise E4/DRSP, a combined oral contraceptive, in the United States. The product is expected to be launched in first half of calendar 2021, subject to US Food and Drug Administration (FDA) approval. On approval the product is expected to receive five-year New Chemical Entity (NCE) exclusivity from the FDA, with potential for patent protection beyond 2030.

E4/DRSP is a novel, next generation combined oral contraceptive composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Estetrol (E4) is a native estrogen produced by the human foetal liver during pregnancy. Following more than 20 years of research and development, Mithra can now produce Estetrol (E4) at scale through a complex plant-based production process.

Mayne Pharma's CEO, Mr Scott Richards said "I am excited to announce the addition of E4/DRSP, a next generation oral contraceptive, to our specialty brand portfolio and further strengthen our relationship with Mithra, who is also our partner for generic NUVARING. This transaction transforms Mayne Pharma and is highly consistent with our stated strategy to build our specialty business with durable, high growth novel products in core therapeutic categories leveraging our commercial capability and associated know-how in the US."

"If approved, Estetrol (E4) will be the first native estrogen approved in a contraceptive product in the US and the first new estrogen introduced in the US in approximately 50 years. E4/DRSP is an



innovative contraceptive with a unique mode of action that phase II and phase III studies suggest could result in improved patient outcomes. This product is expected to be a foundation asset in Women's Health for many years to come and has a strong and synergistic fit with Mayne Pharma's currently marketed portfolio of more than 20 branded generic contraceptives and existing pipeline products such as generic NUVARING for which we are targeting approval in calendar 2020."

"Women's Health is a core therapeutic area for the company and this deal enables Mayne Pharma to accelerate and extend its position in this specialty. We are attracted to the underlying fundamentals of the US short-acting combination contraceptive market (estrogen + progestin) in terms of its stability and scale with more than 10 million American women using combination oral contraceptives, patches or vaginal rings every day."

Mithra's CEO, Mr Francois Fornieri said "We are delighted to sign this landmark agreement and believe Mayne Pharma is the best possible partner for the commercialisation of E4/DRSP in the US. Mithra and Mayne Pharma have been partners since 2017 and we look forward to helping Mayne Pharma maximise the potential of its Women's Health franchise in the US."

In two phase III clinical studies conducted in 3,725 women, E4/DRSP showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability.

The US contraceptive market is valued at US\$5.4 billion according to IQVIA with the short acting combined hormonal contraceptives¹ (CHCs) component estimated at US\$4.0 billion and approximately 135 million units sold annually². The brand market for CHCs represent 56% of the value with the top four products being NUVARING contraceptive ring with US\$960 million in annual sales, LO LOESTRIN[®] FE oral contraceptive with US\$800 million, XULANE[®] contraceptive patch with US\$290 million and TAYTULLA[®] oral contraceptive with US\$170 million in annual sales, according to IQVIA³.

Transaction structure and financial impacts

Under the terms of the agreement, Mayne Pharma will pay up to US\$295 million comprising US\$8.75 million in cash and 4.95% of Mayne Pharma's ordinary shares at closing. Mayne Pharma will also pay US\$11 million in cash and a further 4.65% of Mayne Pharma's ordinary shares following FDA approval (based on issued shares at closing), plus contingent payments based on reaching cumulative net sales targets⁴. The total consideration of US\$295 million would be paid if cumulative net sales of E4/DRSP exceed US\$2.25 billion. In addition, there is a transfer price comprising fixed and variable component based on a percentage of net sales over the term of the license.

¹ CHCs contain estrogen plus progestin and are short-acting oral contraceptives, vaginal rings or patches.

² IQVIA, MAT Sales and NSP Units July 2019. A single unit is equivalent to one 28-day cycle.

³ Annual net sales of NUVARING and LO LOESTRIN FE in the US in 2018 were US\$722 million and US\$528 million respectively.

⁴ Actual number of shares issued at closing and regulatory approval is 168.9 million and is based on 9.6% of the expanded capital base. The equity value at closing is US\$28.7 million based on 83.1 million issued shares, AUD:USD rate of 0.675 and a 10-day VWAP share price of A\$0.511.



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Completion is subject to the parties making a filing with US Federal Trade Commission (FTC) and expiration of the 30-day waiting period associated with the filing. The shares issued to Mithra are subject to a two-year lock up period from the date of closing⁵. The agreement also includes a future seat on Mayne Pharma's Board following regulatory approval of E4/DRSP (subject to Mayne Pharma shareholder approval) and participation on a joint steering committee relating to the commercialisation and continued development of E4/DRSP.

Mayne Pharma's Chairman, Mr Roger Corbett said, "This agreement further strengthens our strategic partnership with Mithra, a company dedicated to the development of Women's Health products and enables additional collaboration opportunities between the companies. We welcome the nomination by Mithra of a new Board member who will meet our agreed criteria at regulatory approval as part of their equity investment which is expected to be 4.95% at closing and 9.6% of the share base following regulatory approval of E4/DRSP."

The product is expected to be EBITDA positive in its first full financial year following approval with peak net sales potential in excess of US\$200 million per year.

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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, 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 potent compounds, controlled substances, modified-release products and inherently unstable compounds.

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.

⁵ Subject to certain limited exceptions



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Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at www.mithra.com.

Mithra has signed 8 other licensing deals for E4/DSRP with a number of leading Women's Health companies covering Europe, Japan, Russia, Brazil, Canada, Middle East, North Africa and Southern Africa.

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