



## Mithra Signs License and Supply Agreement with Mayne Pharma for Commercialization of Estelle in Australia

- Consolidation of partnership with Mayne Pharma for commercialization of the combined oral contraceptive E4/DRSP (Estelle®<sup>1</sup>) in Australia
- Mithra eligible for milestone and license fees of up to EUR 3.5 million
- Preparation ongoing for the commercial launch of Mithra's oral contraceptive in the U.S. and Australia, targeted for H1 and H2 2021 respectively

Liege, Belgium, 28 May 2020 – 8:15 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces it has entered into an exclusive 20-year license and supply agreement with Mayne Pharma Group Limited ("Mayne") for the commercialization of its combined oral contraceptive E4/DRSP (Estelle) in Australia.

Estelle is a novel, next generation oral contraceptive product candidate containing Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg, with a unique benefit/risk profile. E4 is a naturally occurring estrogen that is produced by the human foetal liver during pregnancy. Following many years of research and development, Mithra can now produce E4 at scale through a complex plant-based production synthesis process.

Under the terms of the agreement, Mithra is eligible to receive down payment and milestone fees of up to EUR 3.5 million following signing, regulatory approval, commercial launch and achieving cumulative net sales targets. Mithra will also receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ) in addition to other revenues on net sales. Based on market assumptions and Mithra's forecast, this agreement represents a deal worth up to EUR 40 million over the period.

The Australian contraceptive market is valued at EUR 77 million with the short acting combined (estrogen + progestin) hormonal oral contraceptives estimated at EUR 42 million with approximately 14 million units sold annually<sup>2</sup>. The product is expected to be filed with the Australian agency TGA in 2020 and launched 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 has the option to obtain a license to register and launch the product in New Zealand.

**François Fornieri, CEO Mithra Women's Health, commented:** *"We are delighted to have further strengthened our strategic relationship with Mayne Pharma to now bring our oral contraceptive 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"*

**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. This product has a unique mode of action that has shown promising results in the Phase 3 clinical studies conducted in 4,400 women with positive*

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<sup>1</sup> Benelux registered trademark. Mayne Pharma will market the product under a different trademark in Australia.

<sup>2</sup> IQVIA, MAT Sales and units, Dec 2019. A single unit is equivalent to one 28-day cycle.

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 Mithra's vaginal contraceptive ring 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."

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### For more information, please contact:

**Alexandra Deschner (IRO)** : +32 490 58 35 23 - [investorrelations@mithra.com](mailto:investorrelations@mithra.com)

**Maud Vanderthommen (Press)** : +32 473 58 61 04 – [press@mithra.com](mailto:press@mithra.com)

### 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): Estelle®, 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 100 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

### 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. [www.maynepharma.com](http://www.maynepharma.com)

### About Estelle®

Estelle® is Mithra's novel combined oral contraceptive (COC) product candidate based on Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg. E4 is a native estrogen that is produced by the human fetus, passing the maternal blood at relatively high levels during pregnancy. In two phase III clinical studies conducted in 4,400 women, Estelle® showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. Mithra has signed 10 licensing deals for Estelle® with a number of leading women's health companies covering United States, Europe, Japan, South Korea, ASEAN, Russia, Brazil, Canada, Middle East, North Africa, Southern Africa and Australia.

### 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.*

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