



MITHRA SIGNS LANDMARK CONTRACT FOR ESTELLE® IN THE UNITED STATES WITH MAYNE PHARMA

- **Historical agreement with Mayne Pharma, who became the second largest supplier of oral contraceptives in the US after the acquisition of a portfolio of branded generic products from TEVA in 2016**
- **Record deal value for Estelle®. Potential gross revenues in Mithra's worst-case scenario at a minimum of EUR 4,5 billion, which represents more than twice the size of European deal**
- **Mithra eligible for license fees of at least USD 295 million**
- **Mithra to be awarded 9.6% equity stake across two tranches in Mayne Pharma**
- **CDMO cross fertilization opportunities for both companies**

Liege, Belgium, 01 October 2019 – 13:00 CEST – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, is very pleased to announce that it has signed a License and Supply Agreement (LSA) with Mayne Pharma Group Limited (hereinafter referred to as "Mayne"), a leading Women's Health player in oral contraceptives in the United States (US), for an exclusive license to commercialize Estelle® in the US. Estelle® is Mithra's novel combined oral contraceptive (COC) product candidate based on Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg, with a unique benefit/risk profile. 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 E4 at scale through a complex plant-based (soja) production synthesis process.

Under the terms of the agreement, Mithra will receive down payment and milestone fees in equity & cash of at least USD 295 million. In addition to that, a transfer price comprising fixed and variable components based on a percentage of high double-digit net sales over a 20-year period. Mithra will be issued 9.6% of Mayne's Ordinary Shares across two tranches: the first tranche of equity will represent 4.95% of Mayne's total equity on issue; the second tranche will be awarded on FDA approval of the product¹. The collaboration also includes a future seat on Mayne's Board of Directors upon FDA approval of Estelle®, as well as participation on a joint steering committee relating to the commercialization and continued development of Estelle®. Moreover, Mithra will exclusively supply Estelle® for Mayne and shall manufacture it at its CDMO² in Belgium.

Currently, the total US contraceptives market is valued at approximately USD 5.4 billion annually (51% attributed to combined oral contraceptives (COCs)), double the size of the European market³. It will be a significant revenue generation opportunity for both Mithra and Mayne across the 20-year term of

¹ The two tranches comprise 168.9 million shares in total with 83.1 million to be issued at transaction close, and 85.8 million upon FDA approval of the Product.

² Contract Development and Manufacturing Organization

³ IQVIA July 2019

the license. According to Mithra's worst-case scenario, gross revenues should reach around € 4,5 billion during the 20-year term of the contract.

Mayne is an ASX-listed specialty pharmaceutical company with around 1000 employees focused on the application of drug delivery expertise to commercialize branded and generic pharmaceuticals. Mayne became the 2nd largest supplier of oral contraceptives in the US after the acquisition of a portfolio of generic products from TEVA Pharmaceuticals Industries Limited (Teva) in August 2016. Mayne's strategic priorities are focused on creating long term sustainable value via their multi-channel commercial approach of marketing innovative and generic products in key therapeutic categories such as women's health.

With its two plants in US and Australia, Mayne also provides contract development and manufacturing services in the formulation of complex oral and topical dose forms to more than 100 clients worldwide. In Belgium, Mithra CDMO is one of a handful of companies in the world that are able to develop multiple drug-delivery systems under one roof, i.e. polymers, implants, sterile injectables and hormonal tablets. This agreement further entrenches our strategic partnership with Mayne and enables additional collaboration opportunities between the companies in the near future.

Mayne and Mithra will work together on the regulatory submission planned by end 2019 with projected commercial launch of Estelle® in the first half of calendar 2021, subject to FDA approval. Estelle® would 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. On approval the product is expected to receive five-year New Chemical Entity (NCE) exclusivity from the FDA, with potential for patent protection until 2036 vs 2029 today. This new agreement, the largest in Mithra's history, confirms the aligned strategies of the two companies in Women's Health and the opportunity to unlock value for both sets of shareholders through this unique partnership with Estelle® and in the wider oral contraceptive field with E4 in the US.

François Fornieri, CEO of Mithra, commented: *"On the occasion of our 20th year anniversary, we are delighted to sign this highly anticipated landmark agreement with Mayne for the commercialization of Estelle® in the United States. This is by far the largest contract in Mithra's history, and we are very happy with the unique deal terms negotiated. Mayne is a key player in the US contraceptives market following its 2016 acquisition of Teva's generics portfolio. With strong management experience in women's health and the upcoming launch of our vaginal ring Myring™ in the US, we are certain that Mayne is the best possible partner for the commercialization of Estelle®. Through a key shareholder position and an active participation on Mayne's Board of Directors, Mithra will be involved in the deployment of Estelle's® commercial strategy in the world's largest market."*

Scott Richards, CEO of Mayne Pharma, commented: *"I am excited to announce the addition of Estelle®, a next generation oral contraceptive to our specialty brand portfolio and further strengthen our relationship with Mithra, who is also our partner for generic Myring™. 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. 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."*

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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 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. Mithra has signed 9 licensing deals for Estelle® with a number of leading women's health companies covering Europe, Japan, South Korea, ASEAN, Russia, Brazil, Canada, Middle East, North Africa, Southern Africa and United States.

About Mithra

Mithra (Euronext: MITRA) 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 Estelle®, 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

About Mayne Pharma

Mayne Pharma is a publicly traded specialty pharmaceutical company listed on the Australian Securities Exchange (ASX: MYX). The company applies its drug delivery expertise to commercialize branded and generic pharmaceuticals. 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 its technologies have been successfully commercialized in products marketed around the world. Mayne Pharma has two product development and manufacturing facilities based in Greenville, North Carolina, USA, and Salisbury, Australia, and offers expertise in formulation of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

Important information regarding forward-looking statements

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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