

Mithra Provides Supplementary Details on Estelle® US Deal with Mayne

Liege, Belgium, 3 October 2019 - 7:30 CEST - Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today provides supplementary details related to the US deal with Mayne Pharma for Estelle[®].

Under the terms of the 20-year agreement, Mithra will receive:

- Minimum of USD 295 million (USD 308.1 million actualized) in license fees, comprised of milestone fees in cash and in equity (+ USD 13.1 million actualized¹), plus
- Fixed supply price per product, and a
- Variable supply price based on a percentage (high double-digits) of net sales.

Mithra would additionally like to clarify the difference between gross and net sales in the US, compared to Europe and the Rest of the World. According to IQVIA analysis for Estelle®, the net sales are equal to 65% of the gross sales. In Mithra's "worst-case" scenario, net sales represent 50% of gross sales. For example, if Estelle®'s retail price is comparable to our benchmark Yaz/Yasmine®, which retails on average for \$200 per cycle in the US, the net price to Mayne would be approximately \$100 per cycle.

As per Mayne's press release this morning, "peak net sales potential to exceed USD 200 million per annum", which equates to Mithra's worst-case scenario of EUR 4.5 billion gross sales over the duration of the 20-year contract period. According to Mayne's analyst estimates, peak sales will be reached early on, by 2024/25². Market trends in the US point to a steady price increase year-over-year.

Furthermore, this worst-case scenario is based on a market share of only 1.9% in volume of the combined oral contraceptives (COC) market in the US. In contrast, our reference market drospirenone (DRSP) grew from 9% to 11%³ in volume over the last year (+18%).

Estelle®, which contains DRSP, differentiates itself because of its novel, native estrogen, Estetrol (E4). With its unique mode of action, E4 has a minimal impact on liver cells and metabolic pathways, including on the coagulation parameters⁴ resulting in an overall beneficial hemostatic profile. These coagulation parameters are effected more negatively by Ethinyl-Estradiol, present in most oral

⁴ Kluft C et al., Contraception 2017; 95(2):140-7

https://investors.mithra.com/wp-content/uploads/2018/03/2018-03-08-Hemostasis-ISGE-en-final.pdf

¹ At closing on 2 October 2019 (ASX: MYX)

² Analyst reports Macquarie/Credit Suisse, 2 October 2019

³ IQVIA January 2019

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contraceptives. Today, 30% of US women are not taking the pill mainly due to safety or convenience⁵. With its unique benefit/risk profile, Estelle could be a promising new contraceptive solution.

Mithra is convinced that Mayne is the best possible partner for the commercialization of Estelle® in the US. According to Mayne's CEO, Scott Richards, "this product (Estelle®) 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."

As part of their marketing strategy, Mayne has committed to invest several hundred million USD over the first five years, to cover all expenses. Their head of medical affairs will be 80% dedicated to the Estelle® project, hiring four medical scientific liaisons geographically distributed around the country, hired between February and April 2020. According to current estimates, it will take a fully dedicated Estelle® team of ~70 experienced sales representatives and 8 managers, at a minimum. In addition, Mayne will work with the Mithra team and other international partners on branding and promotional materials over the next year, with a largely digital approach.

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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 <u>www.mithra.com</u>

Important information

The contents of this announcement include statements that are, or may be deemed to be, "forwardlooking 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

⁵ K. Daniels et al., National Health Statistics report n° 62, 2013

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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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