



Mithra Signs LSA for Commercialization of Estelle® in North Africa

- Mithra grants exclusive license to GyneBio Pharma for commercialization of its combined oral contraceptive Estelle® in Algeria, Morocco and Tunisia
- Deal worth up to EUR 25 million for Mithra over the contract period
- Agreement follows licensing deals for Estelle® with market leaders in key regions such as U.S., Europe, Australia, South America, ASEAN and Middle East

Liege, Belgium, 19 October 2020 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that it has entered into an exclusive license and supply agreement with Gynebio Pharma for the commercialization of Estelle® in North Africa. 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.

Based in Casablanca, GyneBio Pharma is a leading Women's Health company in North Africa. It commercializes the most sold contraceptive pill in Morocco and has just commissioned the first hormonal plant in Morocco. Gynebio Pharma partners with top International players to market Women's Health products in North Africa and also offers best-in-class hormonal production services.

Under the terms of this 20-year agreement, Gynebio Pharma will distribute Estelle® in Algeria, Morocco and Tunisia, where Estelle's® benchmark market (EE/DRSP) is rapidly growing and worth approximately EUR 5.7 million per year¹. Mithra will receive an upfront payment and will be eligible to receive milestone payments, sales-related milestones and recurring revenues based on minimal annual quantities (MAQ). This agreement represents a deal worth up to EUR 25 million over the period for Mithra.

The agreement with GyneBio Pharma follows a number of licensing deals for Estelle® with key commercial partners in the United States, Europe, Russia, Canada, Australia, Brazil, Japan/ASEAN, South Korea, Hong-Kong, Taiwan, South Africa, Israel, Middle East and North Africa.

François Fornieri, CEO Mithra Women's Health, commented: "We are pleased to have finalized the agreement with GyneBio Pharma for the commercialization of our contraceptive Estelle® in North Africa. Following the landmark deal signed with Mayne Pharma for the United States and recently for Australia, we continue to extend Estelle's licenses with best-in-class partners to maximize the potential of our innovative product in core territories. Filing of Estelle® has already been accepted by both US and European regulatory agencies, and we are currently manufacturing the safety stock ordered by our partners. In parallel, we are working in tandem with our partners on the commercial roll-out strategy of Estelle®, in order to be ready for commercialization, which is expected in the first half of 2021".

Abdelhakim Tahri, CEO Gynebio Pharma, commented: "We are very proud to bring Estelle®, the new era in contraception, to North African women and we are happy to collaborate with Mithra. Through this new

¹ IQVIA 2019, CAGR 5.81% (2014-2019)

partnership, Gynebio confirms once again its ambition to improve the quality of life of female patients by providing best-in-class products”.

For more information, please contact:

Alexandra Deschner (IRO - Mithra) : +32 490 58 35 23 – investorrelations@mithra.com

Carole Kousis (Press - Mithra) : +32 4 348 28 22 – press@mithra.com

Mamoun Tahri (Strategy & Development – Gynebio) : +212 661 22 60 73 – mamoun.tahri@gynebiopharma.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 targeting 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

About Gynebio

Gynebio Pharma is an affiliate of Cooper Pharma, leading pharmaceutical company in Morocco and key player in Africa and in the Middle East. Offering more than 100 pharmaceutical specialties of its own generics portfolio in the major therapeutic areas, Cooper Pharma also manufactures, imports, markets and promotes more than a hundred drugs licensed-in from over 20 international companies. Gynebio Pharma was founded by Abdelhakim Tahri, Gynebio’s CEO who has more than 30 year experience in Women’s Health including as Regional General Manager of Organon where he was in charge of the launch of various innovative contraceptive pills (Marvelon, Mercilon....). www.gynebiopharma.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 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 11 licensing deals for Estelle[®] with a number of leading women’s health companies covering United States, Canada, Europe, Russia, Australia, Japan, South Korea, ASEAN, Brazil, Middle East, North Africa and Southern Africa.

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.

A circular logo with a teal background and white text that reads "News Alerts".

News
Alerts

Subscribe to our mailing list on investors.mithra.com to receive our press releases by email or follow us on our social media :

[Linkedin](#) • [Twitter](#) • [Facebook](#)