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# Mithra Signs LSA with Alvogen for Commercialization of Estelle® in Hong Kong and Taiwan

- Mithra grants exclusive license to Alvogen for commercialization of its combined oral contraceptive Estelle® in Hong Kong and Taiwan
- Agreement follows licensing deals for Estelle® with market leaders in U.S., Europe, Russia, Canada, Brazil, Japan, South Korea, Middle East and South Africa

Liege, Belgium, 6 January 2020 - 7:30 CET - Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that it has signed an exclusive license and supply agreement with Alvogen for the commercialization of Estelle® in Hong Kong and Taiwan. Estelle® is Mithra's novel combined oral contraceptive (COC) product candidate, containing 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

Alvogen is a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brand, over-the-counter brands (OTC) and biosimilar products for patients around the world. Alvogen has commercial operations in 35 countries with 2,800 employees and operates four manufacturing and development hubs in the U.S., Romania, Korea and Taiwan.

Under the term of this 20-year agreement, Alvogen will distribute Estelle® in Hong Kong and Taiwan where the hormonal contraception market is worth approximately EUR 20 million per year. More than half of the market is dominated by DRSP/EE, Estelle's® benchmark1. Mithra will receive down payments, sales-related milestones, royalties and recurring revenues bases on Minimal Annual Quantities (MAQ). Moreover, Mithra will manufacture Estelle® at its Contract Development and Manufacturing Organization facility in Belgium.

This agreement follows a number of licensing deals for Estelle® with key commercial partners in leading markets, including the United States, Europe, Russia, Japan/ASEAN, Brazil, Canada, South Africa, South Korea, Israel and Middle East.

François Fornieri, CEO Mithra Women's Health, commented: "We are pleased to have finalized the agreement with Alvogen for the commercialization of our contraceptive Estelle® in Hong Kong and Taiwan. After the landmark deal signed in October with Mayne Pharma for the United States, we continue to extend Estelle's licenses with best-in-class partners to maximize the potential of our innovative product in core territories".

Commenting on the transaction, Petar Vazharov, Executive Vice President of Alvogen APAC, said: "Strengthening our Asian presence with branded assets is an integral part of our persistent efforts to generate growth and establish economies of scale in the Asia Pacific region. We are positive that the innovation of Estelle® is a strong addition to our women healthcare focus here in Asia."

<sup>&</sup>lt;sup>1</sup> IQVIA 2018 Data

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#### **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 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. www.mithra.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 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 Alvogen**

Alvogen is a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brand, over-the-counter brands (OTC) and biosimilar products for patients around the world. Alvogen has commercial operations in 35 countries with 2,800 employees and operates four manufacturing and development hubs in the US, Romania, Korea and Taiwan. North America is Alvogen's single largest market, other key markets include: South Korea, West Balkan, Poland, Romania, Bulgaria, Hungary, Taiwan, Ukraine, Russia, Japan and China.

## 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 forwardlooking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.