



## MITHRA ANNOUNCES COMPLEX THERAPEUTICS UPDATE

- **Positive study results from three-month formulation of Zoreline<sup>®</sup>, allowing progression to final clinical studies**
- **Pivotal trial will commence in Q1 2019, as previously expected**
- **Licensing agreement signed with UAE<sup>1</sup>-based ITROM Pharmaceutical Group**

**Liège, Belgium, 21 December 2018** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces positive results from its three-month PK Zoreline<sup>®</sup> study, and a licensing agreement for two products with UAE-based company ITROM Pharmaceutical Group (ITROM).

### Zoreline<sup>®</sup> pilot study update

Having previously announced positive PK results for the one-month formulation of Zoreline<sup>®</sup>, the company's product candidate for branded Zoladex<sup>®</sup> (AstraZeneca), in February 2018, Mithra has now received positive results for the three-month injectable formulation. The study results demonstrated that Zoreline<sup>®</sup> had a similar profile to the three-month (10.8 mg) Zoladex<sup>®</sup> implant. Zoladex<sup>®</sup> is a biodegradable, injectable luteinizing hormone-releasing agonist, used to treat prostate cancer, breast cancer and benign gynecological disorders. The product exists as a one- and three-month implant, containing 3.6 mg and 10.8 mg of goserelin, respectively. The positive three-month Zoreline<sup>®</sup> PK study data received this month enables Mithra to initiate a pivotal clinical pharmacodynamic study on the three-month and one-month formulations in Q1 2019 and Q4 2019 respectively as planned, with a view for filing to obtain marketing authorization thereafter.

Zoreline<sup>®</sup> represents an important commercial opportunity: in 2017, total sales for Zoladex<sup>®</sup> amounted to USD 693m globally<sup>2</sup>. With the exception of a couple of Eastern European countries<sup>3</sup>, no generic version of Zoladex<sup>®</sup> has been approved to date. Moreover, the one-month implant accounts for over 55% of the sales volume<sup>4</sup>. It is typically used as a starting treatment to check prostate and breast cancer patients' tolerability for goserelin, after which the treatment can be continued with the three-month formulation (10.8 mg). The one-month treatment is also prescribed for certain gynaecological disorders, such as endometriosis and uterine fibroids, while the three-month treatment is mainly used in prostate cancer.

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<sup>1</sup> UAE : United Arab Emirates

<sup>2</sup> IMS Health Q3 2017

<sup>3</sup> In 2016, Reseligo™ was launched by Alvogen in selected Central & Eastern European countries.

<sup>4</sup> IMS Health Q3 2015

## Licensing agreement with ITROM Pharmaceutical Group

In addition to the positive study data, Mithra has signed a licensing agreement with UAE-based company ITROM for two products, Tibelia (tibolone) and Daphne Continu<sup>5</sup>. Combined, the products will generate at least €8m of value to Mithra over the ten years of the deal. Under the terms of the deal, Mithra will be responsible for registering the products in Belgium, and ITROM will handle the regulatory procedure in MENA territories, and distribute the products in Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, Qatar, Oman, Lebanon and Jordan. The hormonal contraceptive market in the MENA region was worth €37.5m in 2017, whilst the overall hormonal menopause market<sup>6</sup> was worth €2.65m.

ITROM is a UAE-based Pharma group specializing in breakthrough healthcare, with women's health placed at the forefront of their activities. Its aim is to bring innovative and safe alternatives to women in the areas of fertility, contraception, Hormonal Therapy (HT) and personal care, with a parallel focus on ophthalmology, pediatrics and ENT in its other emerging lines. Through leveraging Mithra's women's health portfolio, ITROM plans to expand its business in the MENA region and to enlarge its footprint in the area, addressing both the contraception and menopause markets with Tibelia and Daphne Continu.

**François Fornieri, CEO of Mithra Women's Health, commented:** *"December has continued to be a busy month of progress for Mithra. The second Zoreline PK study strengthens our product candidate profile, allows us to proceed to the last development step before filing, and should also support our commercial partnering efforts. Our agreement with ITROM is an important step into the MENA market, and with their growing focus on expanding their women's health offering, we look forward to a long and productive partnership together."*

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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 fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates – a fifth generation oral contraceptive Estelle<sup>®</sup> and next-generation hormone therapy Donesta<sup>®</sup> - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets 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 Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at: [www.mithra.com](http://www.mithra.com)

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<sup>5</sup> Daphne Continu (21 + 7)

<sup>6</sup> IMS Health Q3 2017, excluding Bahrain, Qatar and Oman

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