



## **MITHRA SIGNS EXCLUSIVE LICENSE AND SUPPLY AGREEMENT WITH ADCOCK INGRAM FOR COMMERCIALIZATION OF ESTELLE® IN SOUTHERN AFRICA**

- **Mithra is eligible for a downpayment of EUR 1.5 million**
- **20-year exclusive license and supply agreement to generate annual recurring revenues and royalty payments**
- **Production at the Mithra CDMO facility**
- **Deal forms part of Mithra's strategy to realise the full potential of the pipeline programs through global partnerships with leaders in Women's Health**

**Liège, Belgium, 30 October 2018** – Mithra (Euronext Brussels: MITRA) today announced that it has entered into an exclusive license and supply agreement with Adcock Ingram to commercialize Estelle®, a combined oral contraceptive (COC), containing 15 mg Estetrol (E4) / 3 mg drospirenone (DRSP), in Southern Africa<sup>1</sup>. The product is a novel combined oral contraceptive with natural, native estrogen acting selectively in tissues combined with DRSP's non-contraceptive benefits.

Under the terms of the exclusive 20-year agreement, Mithra is eligible to receive a downpayment of EUR 1.5 million. Mithra will also be eligible to receive additional commercialization milestone payments. Further sales-related royalties will be payable to Mithra subsequent to the launch of the product. Moreover, Mithra will receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ), single digit tiered royalties on net sales and additional high double digit royalties on sales exceeding forecasts. Moreover, Mithra will produce Estelle® for Southern Africa at its CDMO facility in Belgium.

Adcock Ingram is a leading South African-based pharmaceutical company listed on the Johannesburg stock exchange (AIP:SJ) with a market cap of approximately ZAR 10.56 Bn (EUR 610 million). Adcock Ingram manufactures, markets and distributes a broad range of healthcare products and provides a wide range of women's health quality treatment options that meet the needs of women through specific stages of their lives. Adcock Ingram is a leading company in this class with its portfolio of hormone therapy products. The addition of Estelle® will further expand its Women's Health footprint. The company covers over 13 markets in the rest of Africa and is the second largest supplier to the private sector.

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<sup>1</sup> Adcock will commercialize the product under a different brand name.

The territories under the agreement include South Africa, Botswana, Lesotho, Swaziland, Mozambique, Zimbabwe and Namibia, representing a value of over EUR 40.0 million<sup>2</sup>, making this a key region for the commercialization of Estelle<sup>®</sup>. Combined oral contraceptives (COCs) in South Africa alone account for around 63% of the EUR 40 million market. DRSP-based COCs (including the Yaz<sup>®</sup> product family<sup>3</sup>) have a market share in South Africa of around 51%. Based on the improved safety profile seen in clinical trials to date, Mithra and Adcock Ingram believe Estelle<sup>®</sup> has the potential to achieve a significant share of the COC market.

**François Fornieri, CEO of Mithra Women’s Health commented :** *“We are very pleased to have agreed terms with Adcock Ingram for the commercialization of our next generation oral contraceptive product candidate Estelle<sup>®</sup> in Southern Africa. This is our first agreement in this region and Adcock Ingram’s specialization in women’s health makes them an ideal partner. Today’s news further reinforces our confidence in our ability to sign a future partnership for Estelle<sup>®</sup> in the US, where the oral contraceptive market is valued at twice the size of the European market.”*

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### About Estelle<sup>®</sup>

Estelle<sup>®</sup> is Mithra’s novel oral contraceptive product candidate composed of 15 mg Estetrol (E4), its unique native estrogen, and 3 mg drospirenone (DRSP). The E4 Freedom studies are open-label single arm trials to assess the safety and efficacy of Estelle<sup>®</sup> in over 1,550 participants in Europe/Russia and approximately 2,000 participants in the US/Canada, over a period of 13 cycles. Mithra recently announced positive top-line results for its pivotal EU/Russia Phase III study, with the top-line results of the US/Canada study to follow in Q1 2019.

### 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 natural 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)

### About Adcock Ingram

Adcock Ingram is a leading South African pharmaceutical manufacturer, listed on the Johannesburg Stock Exchange. The Company manufactures, markets and distributes a wide range of healthcare

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<sup>2</sup> IMS Analytics Link Q3/2017.

<sup>3</sup> Yaz<sup>®</sup> is a registered trademark from Bayer healthcare

products. The company is a leading supplier to both the private and public sectors of the market. Adcock Ingram started as a small Krugersdorp pharmacy, after which its founders branched out into new product development, manufacturing, distribution, and sales and marketing. Adcock Ingram was first listed on the Johannesburg Stock Exchange (JSE) in 1950 and enjoyed blue chip status. In 2000 Tiger Brands (then the majority shareholder) acquired the minority shares, and Adcock Ingram was delisted from the JSE and operated as a wholly owned subsidiary of Tiger Brands. On 25 August 2008, Adcock Ingram was unbundled from Tiger Brands and relisted on the JSE. More information can be found at <http://www.adcock.co.za/>

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**Important information**

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