

Joint Press Release



MITHRA AND LOTUS ANNOUNCE APPROVAL OF ALYSSA[®], AN INNOVATIVE ORAL CONTRACEPTIVE, IN BOTH TAIWAN AND HONG KONG

- **ALYSSA[®], developed by Mithra, is the first and only oral contraceptive drug containing estetrol, a native estrogen (E4) and drospirenone (DRSP), which features strong efficacy, safety and tolerability with excellent cycle control**
- **Under the partnership with Mithra, Lotus will be exclusively marketing ALYSSA[®] in both Taiwan and Hong Kong to pursue overall contraceptive market worth US\$25 million, growing at a 3-year CAGR of 11% since 2019**
- **Lotus anticipates the commercial launch of ALYSSA[®] contraceptive pill by the first quarter 2023 in Taiwan, followed by Hong Kong later in the year**

21 September 2022, 7:30 CEST – Taipei City, Taiwan and Liege, Belgium – Lotus Pharmaceutical Co., Ltd. (TWSE: 1795, “Lotus”) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA, “Mithra”) today are pleased to announce that Estelle[®], the first-of-its-kind oral contraceptive with a novel estrogen developed by Mithra, has been approved by both Taiwan Food and Drug Administration (TFDA) and Hong Kong Drug Office, Department of Health, under the trademark ALYSSA[®]. Through this partnership with Mithra, Lotus will be exclusively marketing the product in Taiwan and Hong Kong.

Already commercialized globally, including major markets such as the US, Canada, Australia and several European countries, ALYSSA[®] is the first ever oral contraceptive pill to combine the native and selective estrogen, estetrol (E4) with drospirenone (DRSP). E4 is a naturally occurring estrogen produced by the human body during pregnancy, and, in ALYSSA[®], E4 is derived from a plant source. Thanks to E4’s unique pharmacologic profile and mechanism of action, ALYSSA[®] has been specifically designed to help overcome the issues associated with synthetic or modified estrogen-based COCs.

Upon launch, ALYSSA[®] will compete in the Taiwanese oral contraceptive market which was valued at US\$14million¹ in 2021 and currently mainly dominated in Taiwan by ethinyl estradiol-based estrogen solutions. Lotus will also market the product in Hong Kong to capture the market potential of approximately US\$11² million as of 2021.

Petar Vazharov, Chief Executive Officer of Lotus, commented: *“We are very excited about our partnership with Mithra to introduce a novel oral contraceptive in Taiwan and Hong Kong markets. Within our existing women healthcare portfolio, the approval of ALYSSA[®] represents an important milestone in providing women with new generation options for their reproductive health. ALYSSA[®] offers an effective, safe, and well-tolerated contraceptive pill with predictable cycle control and has demonstrated low impact on certain parts of the body.”*

¹ MAT Q1 2022, Oral contraception market

² MAT Q1 2022, Oral contraception market

Leon Van Rompay, CEO Mithra Women's Health, commented: *"We are pleased to share the approval received by our partner Lotus for our Estelle® contraceptive in both Taiwan and Hong Kong, which marks our first authorization on the Asian continent. After successfully launching Estelle® in the United States, Canada, Australia and in Europe, these upcoming launches in these two markets further demonstrate Mithra's ability to pursue Estelle®'s business development with best-in-class partners in core territories. Therefore, we are proud to, jointly with Lotus, continue revolutionizing the contraceptive landscape by offering Taiwanese and Hong Kongese women an alternative solution with an optimal benefit/risk."*

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About Lotus Pharmaceutical

Founded in 1966, Lotus (1795: TT) now is the largest pharmaceutical company in Taiwan with high-value generic products covering CNS, CVS, women health, and anti-obesity drugs in tablets and hard/soft gel capsule with a special focus on oral oncology for global markets. By leveraging a best-in-class R&D and manufacturing platform in Asia, Lotus aims to benefit patients, its employees and stakeholders. Furthermore, Lotus can reach nearly every global market with its high value pipeline through its direct markets, currently encompassing Taiwan, Korea, Thailand, Vietnam, Singapore, Hong Kong, Malaysia, Philippines, and China, or via alliances with top-tier pharma companies based on its industry-leading infrastructure certified by most of the advanced regulatory authorities around the world, including US FDA, EU EMA, Japan PDMA, China FDA, and Brazil ANVISA. Lotus International Pte. Ltd. is a wholly-owned subsidiary of Lotus as a regional hub for South East Asian market.

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. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill Estelle®, Mithra is now focusing on its second product 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 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

"ALYSSA® and ESTELLE® are registered trademarks of ESTETRA SRL, a Mithra Pharmaceuticals company.

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



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