

Joint Press Release



MITHRA AND FUJI ANNOUNCE APPROVAL OF NEXTSTELLIS™ IN THAILAND

24 October 2022 – 7:30 CET – Tokyo, Japan and Liege, Belgium – Fuji Pharma Co., Ltd. (Tokyo Stock Exchange:4554, “Fuji”) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA, “Mithra”) today are pleased to announce that OLIC (Thailand) Limited (“OLIC”), a subsidiary of Fuji, has obtained the approval of import license for NEXTSTELLIS™, a novel combination contraceptive containing estetrol and drospirenone (“Product”), for the indication of Contraception. OLIC anticipates the commercial launch of NEXTSTELLIS™ contraceptive pill in Thailand by the end of 2023.

The Product combines the native and selective estrogen, estetrol (E4) with drospirenone (DRSP). Estetrol has been confirmed to act selectively on estrogen receptors, and this selectivity is expected to provide a variety of benefits to the patients. The Product is already commercialized globally, including major markets such as the US, Canada, Australia and several European countries. Under the terms of the agreement signed in August 2016, Fuji has obtained the development and commercialization rights of the Product in Japan and ASEAN countries. A total oral contraceptive market of ASEAN is around EUR 182 million annual sales¹. In Japan, the development name of the Product is FSN-013, and Fuji is currently conducting Phase III clinical trials for FSN-013 for the indication of "Dysmenorrhea" and "Improvement effect on pain associated with endometriosis".

OLIC is one of the largest contract manufacturing organizations (CMO) in the Southeast Asia and is in the middle of transformation from a pure CMO company to a new hybrid company with CMO and pharmaceutical business with own brand products. This approval is the first step in that direction. This approval was conducted for the purpose of importing and selling the Product by OLIC in Thailand.

Takayuki Iwai, President & Chief Executive Officer of Fuji, commented: *“This is an exciting opportunity and a significant global step for Fuji pharma group. The approval will enable OLIC to make NEXTSTELLIS™ available to women across Thailand by the end of 2023. After which, we plan to market the Product in other ASEAN countries through the collaboration with partner companies. Fuji will accelerate the development of the Product to provide patients with new treatment options that contain Estetrol.”*

Leon Van Rompay, CEO Mithra Women’s Health, commented: *“We are pleased to announce this additional marketing authorization for our contraceptive pill in Asia, following the recent approvals for Taiwan and Hong Kong obtained last month. We would like to thank our partner Fuji for this fruitful collaboration, which translates today into an important milestone for our Product in these territories which, considering the two potential indications of contraception and dysmenorrhea, represents a real market opportunity.”*

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Mithra

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About Fuji

Fuji is a Tokyo Stock Exchange (TSE) listed, Japan-based pharmaceutical company mainly engaged in the manufacture and sale of prescription based pharmaceutical products. Since our establishment in 1965, Fuji has promoted corporate philosophy that "We help people lead healthy lives by offering excellent pharmaceuticals." and "Our corporate growth is proportional to our personal growth." Fuji focuses on the field of women's health care with a wide variety of new and generic drugs for women's specific diseases such as infertility, dysmenorrhea, endometriosis, contraception, and menopausal disorders. Fuji aims to be a leading company in women's healthcare and support health of women of all ages.

<https://www.fujipharma.jp/>

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

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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.