

PRESS RELEASE:

November 2, 2021
Fuji Pharma Co., Ltd.

Application by OLIC for import license of FSN-013 in Thailand

Fuji Pharma Co., Ltd. (Headquarter: Tokyo, Japan, President & CEO: Takayuki Iwai “Fuji”) announced today that OLIC (Thailand) Limited (Headquarter: Ayutthaya, Thailand “OLIC”) which is a subsidiary of Fuji has applied and accepted the submission for the import license of FSN-013, a novel combination drug containing Estetrol and Drospirenone, in Thailand to Thai Food and Drug Administration (FDA) for the indication of "Contraception". Fuji has obtained the development and commercialization rights of FSN-013 in Japan and ASEAN countries from Mithra Pharmaceuticals (Headquarter; Liege, Belgium CEO: Leon Van Rompay “Mithra”).

OLIC has been operating as the largest CMO in Thailand, and currently preparing to transform into a pharmaceutical company that manufactures and sells more value-added own-brand drugs. This submission for the import license was conducted for the purpose of importing and selling the developed product FSN-013 by OLIC in Thailand. This is a new approach for Fuji pharma group, which has been manufacturing and selling pharmaceutical products only in Japan. We are also planning to sell FSN-013 in ASEAN countries other than Thailand through the collaboration with ASEAN partner companies.

FSN-013 contains Estetrol (E4), a natural estrogen, as a novel ingredient. Estetrol has been confirmed to act selectively on estrogen receptors, and this selectivity is expected to provide a variety of benefits to the patients. In the U.S., Europe, and other regions, Mithra and its partners have been approved for the indication of "Contraception" sequentially since March 2021. In Japan, we are currently conducting Phase III clinical trials as announced in the ["Initiation of Phase III clinical trials for the developed product \(FSN-013\) in Japan"](#) dated August 3, 2021.

Fuji will accelerate the development of FSN-013 to provide patients with new treatment options that contain Estetrol. We will continue to contribute for improving the well-being of more patients under our corporate philosophy of "We help people lead healthy lives by offering excellent pharmaceuticals."

※For the outline of drug as well as a detailed description of this study, please check the material of the ["New Drug Pipelines Briefing Sessions~To achieve No.1 in Women's Healthcare~"](#).

For further information, contact

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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. Mithra explores the potential of the unique native estrogen Estetrol in a wide range of applications in women health and beyond. 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