

October 18, 2023
Fuji Pharma Co., Ltd.

Submission of a Marketing Approval Application for FSN-013 in Japan

Fuji Pharma Co., Ltd. (hereafter referred to as “Fuji”) and M3, Inc. (hereafter referred to as “M3”) has announced today that Fuji has submitted an application for marketing approval of estetrol/drospirenone combination product (“Product”, Development code: FSN-013), co-developed in Japan, to the Ministry of Health, Labour and Welfare (“MHLW”) as scheduled indication of Dysmenorrhea

Dysmenorrhea is a medical condition that occurs with menstruation during the menstrual period and includes symptoms commonly referred to as menstrual cramps, such as lower abdominal pain and back pain, as well as a tight stomach, nausea, headache, fatigue and weakness, loss of appetite, irritability, diarrhea and depression.

According to “Working Women’s Survey 2021”² conducted by Nikkei BP Intelligence Group Medical & Healthcare Institute “Comfortable Menstruation Project”¹, approximately 70% of working women with symptoms associated with menstruation reported that before and during menstruation symptoms were strong³.

Fuji obtained development and commercialization rights for the Product from Mithra Pharmaceuticals (Headquarters; Liege, Belgium). The Product contains the first natural estrogen from fetal origin called estetrol (E4), which has been confirmed to selectively act on estrogen receptors. This selectivity of E4 is expected to provide a variety of benefits for patients.

In the U.S., Europe, and other regions, the Product is being sold by Mithra and its partners. In Thailand, an ASEAN country, OLIC (Thailand) Limited, a subsidiary of Fuji, began selling the Product under the product name Nextstellis™ in May 2023.

As Fuji and M3 announced “Joint Development and Distribution Agreement for the FSN-013 (dysmenorrhea treatment agent) between M3 and Fuji” on November 12, 2020, Fuji and M3 agreed on the partnership for joint development and commercialization in Japan. Fuji and M3 will accelerate the development of the Product and aim at the launch in 2024 to provide patients with new treatment options by offering FSN-013 that contains estetrol (E4), novel ingredient.

¹. Comfortable Menstruation Project [Seiri Kaiteki Project] (Established in October 2020)
Organized by: Nikkei BP Intelligence Group, Supported by: Fuji Pharma., Co. Ltd. and others
<https://special.nikkeibp.co.jp/atclh/DRS/20/seirikaiteki/>

². Survey on How Menstrual Problems Affect Work and Life of 1,956 Working Women, Nikkei BP Intelligence Group

³. Strong symptoms both before and during menstruation (31.6%), Strong symptom only before menstruation (10.3%), Strong symptom only during menstruation (24.5%), total 66.4%

[About Fuji Pharma Co., Ltd.]

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 healthcare 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.

For further information, please visit our website <https://www.fujipharma.jp/>

[About M3, Inc.]

M3 operates m3.com, a specialized web portal for medical professionals that delivers healthcare related information to its 320,000+ physician members in Japan. Recent business expansions have been in areas such as AI diagnostic tool development and DX of the clinical scene, no longer limited to pharmaceutical marketing. Presence outside of Japan includes the U.S., U.K.,

France, China, Korea, and India, with aggressive business expansion overseas that has amassed 6.5 million physicians across its global platforms. This allows delivery of services including marketing support, marketing research, and job placement support that leverage the platform's value as a media channel.

For further information, please visit our website <https://corporate.m3.com/>

[About Mithra Pharmaceuticals SA]

Mithra (Euronext: MITRA) is a biotech company headquartered in Liège, Belgium, 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. In particular, Mithra are exploring the potential of estetrol, a natural estrogen, not only for women's medicine but also for a wide range of other applications. Mithra is currently developing our second estetrol product, Donesta[®], a next-generation formulation of hormonal therapy, after launching our first estetrol-based product, the oral contraceptive Estelle[®], in 2021. It offers partners a complete initial development through clinical development and specialist manufacturing of Polymeric forms for Complex Therapeutics (vaginal rings, implants), Sterile injectables and Biomedicine (vials, prefilled syringes, cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members.

For further information, please visit our website www.mithra.com.

Note

The financial forecasts and other projections provided in this release are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks. Actual results may differ significantly from these forecasts for a number of reasons. It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification. Information in this release about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

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