

## **Initiation of Phase III clinical trials for the developed product (FSN-013) in Japan**

Fuji Pharma Co., Ltd. (Headquarter: Tokyo, Japan, President & CEO: Takayuki Iwai “Fuji”) announced today that the successful initiation of the Phase -III clinical trials of FSN-013, a novel combination drug containing estetrol and drospirenone for Japanese patients with dysmenorrhea and pain associated with endometriosis. 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”).

The Phase-III study in Japan is aimed at obtaining indications for the treatment of dysmenorrhea and pain associated with endometriosis in Japan.

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. Mithra and its partners earlier announced the approval of this novel combination drug in the US, on April 16, 2021, and Europe on May 20, 2021 for the use in contraception.

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

※For an 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~](#)".

### **[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 (Covid-19, neuroprotection...). 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](http://www.mithra.com)

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