

July 25, 2025  
Fuji Pharma Co., Ltd.

## **Initiation of Phase III clinical trial for the Alyssa<sup>®</sup> combination tablets**

Fuji Pharma Co., Ltd. ("Fuji") announced that the initiation of the Phase -III clinical trial (Study FSN-013P-06) of Alyssa<sup>®</sup> combination tablets for dysmenorrhea in patients with endometriosis in Japan.

Alyssa<sup>®</sup> combination tablets is a dysmenorrhea treatment containing drospirenone and estetrol (E<sub>4</sub>), a natural estrogen in-licensed by Fuji from Gedeon Richter Plc.

Study FSN-013P-06 aims to obtain an indication for the treatment of pain associated with endometriosis in patients diagnosed with endometriosis.

Endometriosis affects approximately one in ten women of reproductive age. It is a disease in which endometrium-like tissue forms in locations other than the uterine lining. About 90% of patients experience menstrual pain, and pain symptoms such as chronic pelvic pain (lower abdominal pain: approximately 70%, lower back pain: approximately 60%), sexual intercourse pain, and defecation pain frequently occur outside of menstruation.<sup>1</sup> These symptoms reduce the quality of life for women.

Fuji Pharma's long-term vision is "Always focusing on creating new value to women's healthcare and contributing to society where everyone can enjoy well-being".

Through the Study FSN-013P-06, we will create new possibilities for E<sub>4</sub> and provide new value to patients.

### **[About estetrol (E<sub>4</sub>)]**

A type of estrogen (natural type) that exists in the body, discovered in 1965. E<sub>4</sub> has a characteristic mechanism of action called NEST (native estrogen with selective action in tissues), showing estrogenic activity on the vaginal and endometrium, bone, vascular system, and brain, while having no effect on breast tissue. E<sub>4</sub> has also been confirmed that the changes in biochemical indices of the blood coagulating fibrinogenolysis system caused by E<sub>4</sub> administration are minor compared to the target drug. Because of its unique mechanism of action, research and development is underway for the use of E<sub>4</sub> for drug treatment other than dysmenorrhea (e.g., menopausal disorders).

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<sup>1</sup> Health Care Lab for Women's Health Promotion, Ministry of Health, Labour and Welfare

**[About Gedeon Richter Plc.]**

Richter aspires to be a global innovator in some key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.7bn and sales of EUR 2.2bn in 2024, it operates Central Europe's largest R&D hub. Its research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen its affordable treatment portfolio. Committed to sustainable growth, Richter invests in R&D, manufacturing excellence, and digitalization to advance medical innovation. Learn more at [www.gedeonrichter.com](http://www.gedeonrichter.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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