

**№** M3, Inc.

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Fuji Pharma Co., Ltd. M3, Inc.

## Positive top-line results in Phase III studies of FSN-013

Fuji Pharma Co., Ltd. (Headquaters: Tokyo, Japan; "Fuji" below) and M3, Inc. (Headquaters: Tokyo, Japan; "M3" below) are pleased to jointly announce the acheivement of positive top-line results from the Phase-III clinical studies evaluating the Estetrol/Drospirenone combination product ("Product", development code: FSN-013) for treatment of Japanese patients with dysmenorrhea or endometriosis.

The double-blind, placebo-controlled studies¹ targeting patients with dysmenorrhea or patients with endometriosis are being performed to obtain an indication for the treatment of dysmenorrhea and pain associated with endometriosis in Japan. The Phase III study in patients with dysmenorrhea (Study No. FSN-013P-03) met its primary endpoint by demonstrating a statistically significant difference for the change in the total dysmenorrhea score when compared to placebo. The other Phase III study in patients with endometriosis (Study No. FSN-013P-04) also met its primary endpoint by demonstrating a statistically significant difference for the change in the Visual Analog Scale² for the most severe pelvic pain (lower abdominal pain / back pain) when compared to placebo. Long term safety (52-week administration) continues to be evaluated for the Product.

Fuji obtained development and commercialization rights for the Product from Mithra Pharmaceuticals (Headquarters; Liege, Belgium). The Product contains the first native 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.

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, novel ingredient.

<sup>&</sup>lt;sup>1</sup> A double-blind, placebo-controlled clinical trial is a trial in which there are two (or more) groups. One group receives the active treatment, the other receives the placebo. All other study conditions are held the same between the two groups such that any difference in their outcome can be attributed to the active treatment and any bias by physicians and/or patients can be excluded.

<sup>&</sup>lt;sup>2</sup> Visual Scale using 100mm line by which patients can evaluate their pain.

## For further information, contact

Fuji Pharma Co., Ltd.

Corporate Communication Section, Corporate Planning Department, Corporate Strategy Division: fsk@fujipharma.jp

Corporate Communication Section, Corporate Planning Department <a href="mailto:fsk\_ir@fujipharma.jp">fsk\_ir@fujipharma.jp</a>

M3, Inc
Public Relations
pr@m3.com

## **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 M3, Inc.

M3 operates m3.com, a specialized web portal for medical professionals that delivers healthcarerelated information to its 310,000+ 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 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 futher information, please visit our website <a href="https://corporate.m3.com/">https://corporate.m3.com/</a>.