

## **Mochida Obtains Marketing Approval in Japan for DINAGEST Tablets 0.5 mg for the Treatment of Dysmenorrhea**

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This material is an English translation of the press release issued on January 23, 2020 in Japanese, and the Japanese release is given priority regarding content and interpretation.

January 23, 2020

Mochida Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan; President: Naoyuki Mochida; hereinafter, Mochida) announced that the company obtained marketing approval in Japan for “DINAGEST Tablets 0.5 mg” (generic name: dienogest; development code: MJR-35) for the treatment of dysmenorrhea on January 23.

DINAGEST Tablets 1 mg, a therapeutic agent for endometriosis, was licensed from Jenapharm, Germany, now a subsidiary of Bayer AG, and developed by Mochida. It has been marketed in Japan since 2008 and an additional indication, reduction of pain caused by adenomyosis, was also approved in 2016.

As dienogest selectively activates progesterone receptors so as to inhibit ovarian function and proliferation of endometrial cells, Mochida developed DINAGEST Tablets 0.5 mg, a low-dose formulation, specifically for dysmenorrhea.

With DINAGEST Tablets 1 mg, Mochida has contributed to the treatment of patients with endometriosis or adenomyosis. Mochida believes that DINAGEST Tablets 0.5 mg, the drug approved this time, will improve the QOL of women troubled with dysmenorrhea.

## Reference

### Summary of the marketing approval

Brand Name	: DINAGEST Tablets 0.5 mg
Generic Name	: Dienogest
Ingredients and Contents	: 0.5 mg dienogest per tablet
Indication	: dysmenorrhea
Dosage and Administration	: Usually, to adults, 1 mg of dienogest is orally administered daily in 2 divided doses, starting from day 2-5 of the menstrual cycle.
Approval Date	: January 23, 2020
Manufacturer/ Distributor	: Mochida Pharmaceutical Co., Ltd.

### About Dysmenorrhea

Dysmenorrhea refers to pathological symptoms accompanied menstruation, such as lower abdominal pain, lower back pain, abdominal bloating, nausea, headache, fatigue and weakness, anorexia, irritation, diarrhea or depression during the menstrual period. According to a survey by the Health and Welfare Sciences Research\* of women aged 20 to 49 years in Japan, menstrual pain, such as lower abdominal or lower back pain, which is a predominant symptom of dysmenorrhea, was observed in 78.6%. Of those surveyed, 32.8% required some sort of medical intervention for menstrual pain, and 12.2% visited a medical institution for the treatment of menstrual pain.

\* "Prevention, diagnosis, and treatment for endometriosis in the perspectives of sexual and reproductive health" (2001); Study report for the Health and Welfare Sciences Research 2000