

Mochida files application for marketing and manufacturing approval of the indication for dysmenorrhea for “Dinagest,” in Japan

This material is an English translation of the press release to be issued on February 8, 2019 in Japanese, and the Japanese release is given priority regarding content and interpretation.

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Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan; President: Naoyuki Mochida; hereinafter, Mochida) announced that the company filed an application for marketing and manufacturing approval of the indication for dysmenorrhea for “Dinagest” (generic name: dienogest; development code: MJR-35) in Japan.

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.

Dinagest is a therapeutic agent for endometriosis, which was in-licensed from Jenapharm, Germany, a subsidiary of Bayer AG, and developed by Mochida. It has been marketed in Japan since 2008. Dinagest also had an additional indication, the reduction of pain caused by adenomyosis in 2016. As dienogest selectively activates progesterone receptors so as to inhibit ovarian function and the proliferation of endometrial cells, it is also expected to have efficacy on dysmenorrhea.

With Dinagest, Mochida has contributed to the treatment of patients with endometriosis or adenomyosis. Mochida is also striving to obtain approval for the application in order to contribute to improving the QOL of women troubled with dysmenorrhea.

* “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