

## **Announcement of approval for an additional indication for therapeutic agent for endometriosis, “Dinagest Tab. / OD Tab.” in Japan**

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This material is an English translation of the press release issued on December 2, 2016 in Japanese, and the Japanese release is given priority regarding content and interpretation.

December 2, 2016

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that Mochida received approval of an additional indication, the reduction of pain caused by adenomyosis, for “Dinagest Tab. 1mg” and “Dinagest OD Tab. 1mg” (generic name: dienogest, hereinafter: Dinagest, therapeutic agent for endometriosis), from the Japanese Ministry of Health, Labour and Welfare (MHLW) on December 2, 2016.

Dinagest, which was in-licensed from Jenapharm, Germany, a subsidiary of Bayer Pharma AG, has been developed by Mochida as a therapeutic agent for endometriosis, and has been marketed since 2008. As it acts to selectively activate progesterone receptors so as to inhibit ovarian function and the proliferation of endometrial cells, it also demonstrates efficacy in the reduction of pain caused by adenomyosis.

Adenomyosis is a disease in which the endometrium-like tissue grows within the myometrium. Patients with adenomyosis often complain of strong menstrual pain that may affect daily living. The peak age of onset is 40-49 years old. Reportedly, 15% to 20% of perimenopausal women have this disease. Curative treatment is surgery (surgical therapy), but if a patient wishes to maintain fertility, there is an option of drug therapy (hormone therapy) to improve clinical symptoms. However, until now there was no drug with a specific indication for adenomyosis, and therefore, a therapeutic agent that could be safely used long term had been anticipated.

Mochida is striving to obtain approval for the application in order to contribute to improving the QOL of women with adenomyosis.

Mochida expects that this will have only a minor impact on its near-term earnings.

## Summary of the marketing approval

The underlined part has been added.

Brand name	: Dinagest Tab. 1mg and Dinagest OD Tab. 1mg
Generic Name	: Dienogest
Ingredients and Contents	: 1 mg dienogest per tablet
Indication	: Endometriosis <u>The reduction of pain caused by adenomyosis</u>
Dosage and Administration	: Usually, to adults, 2 mg of dienogest is orally administered daily in 2 divided doses, starting from day 2-5 of the menstrual cycle.
Manufacturer/Distributor	: Mochida Pharmaceutical Co., Ltd.