

December 25, 2020
Fuji Pharma Co., Ltd.

Application for Marketing Approval of Natural Progesterone Drug Product (FSN-011-01)

Fuji Pharma Co., Ltd. (hereafter referred to as “our company”) has announced today that it has submitted an application for marketing approval of a natural progesterone drug product (oral drug product containing 100 mg of progesterone; product name: FSN-011-01), developed for the treatment of menopausal disorder, to the Ministry of Health, Labour and Welfare (“MHLW”).

This progesterone drug product is used as hormone replacement therapy (“HRT”) that is associated with the treatment of menopausal disorder. When a development recruitment was announced by the “Review Committee on Unapproved or Off-label Drugs with High Medical Needs” led by the MHLW in 2010, Fuji applied for it and commenced development. Thereafter, Fuji has completed a phase III clinical study on Japanese women with menopausal disorder and submitted the application for marketing approval.

Since natural progesterone is poorly absorbed via oral administration, synthetic progesterone drug products are generally used. However, FSN-011-01 is easily absorbed owing to the micronization of natural progesterone.

Fuji expects that this product will provide a new treatment option as HRT for menopausal disorder and will further contribute to well-being of women. Following the application, Fuji will undertake relentless effort to obtain the approval.

For the development of this drug product, Fuji received support from the Pharmaceutical Development Support Center, which is engaged in resolving problems of unapproved drugs and off-label drugs called drug lag.

<< Reference >>

Natural progesterone (oral drug product containing 100 mg of progesterone)

This natural progesterone drug product, containing progesterone as an active ingredient, was developed by Besins Healthcare (head office: Monaco) and has already been approved and marketed in at least 100 countries or regions including the US, UK, and France for the treatment of various diseases that require progesterone supplementation. The International Menopause Society and other societies suggest that natural progesterone has a low risk of causing breast cancer and thrombosis, and it is regarded as an extremely safe product.

Menopausal disorder

The female body is affected by a hormone (estrogen), and its secretion varies considerably depending on the age and reproductive stage of an individual. Various symptoms affecting physical and mental health manifest during the menopausal period, when the amount of estrogen secreted rapidly decreases at a particular age (45–55 years). These symptoms are collectively called “menopausal symptoms (disorder)”

Based on the results obtained from an Internet questionnaire survey* involving 3,888 female general consumers within the menopausal age (40–60 years old), it is estimated that more than half of the women in the menopausal age, approximately 7 million, exhibit menopausal symptoms.

*Report on the results of a survey on menopausal disorder and its symptoms: QLife

Hormone replacement therapy

Since the major cause of menopausal disorder is a decrease in estrogen levels, supplementation of estrogen can improve various menopausal symptoms, including hot flashes. This estrogen supplementation is called hormone replacement therapy. However, it has been confirmed that a single administration of estrogen-containing products increases the risk of developing endometrial cancer in women with a uterus. Thus, co-administration of progesterone has been established as a prophylaxis.

For further information, contact

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