



February 26, 2025

Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)

Submission of New Drug Application for GnRH Antagonist "Linzagolix" Indicated for Uterine Fibroids, in Japan

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto, Nagano, Japan; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announces that today we have submitted a new drug application for approval of manufacturing and marketing in Japan for the GnRH antagonist "Linzagolix" (generic name, development code in Japan: KLH-2109), as indicated for uterine fibroids.

Linzagolix is an orally administered GnRH (gonadotropin-releasing hormone) receptor antagonist. It antagonizes GnRH at the GnRH receptors located in the pituitary gland, thereby inhibiting the secretion of gonadotropins, which are gonadal-stimulating hormones. This reduction in gonadotropin secretion leads to a decrease in estrogen production in the ovaries, thereby improving bleeding and pain symptoms in patients with uterine fibroids. In two domestic phase III clinical trials (KLH2301 and KLH2302 trials) targeting uterine fibroids, Linzagolix demonstrated non-inferiority and superiority to the control group, respectively, and yielded favorable results¹.

In Japan, Kissei is preparing for a domestic Phase III clinical trial for endometriosis. Overseas, Theramex (UK), our licensee, is set to launch the drug for uterine fibroids in Europe in September 2024,² and received approval from the European Medicines Agency (EMA) for the additional indication of endometriosis in November of the same year.³ Additionally, other licensee companies are progressing with development in South Korea and Taiwan.

Kissei is committed to making Linzagolix available to patients worldwide as soon as possible.

The projected financial results for the fiscal year ending March 2025, which incorporate this progress, were disclosed during the announcement of the financial results on November 5, 2024.

1 News Release: July 16, 2024

Results of a Japan Phase III Clinical Trial of the GnRH Antagonist Linzagolix in Patients with Uterine Fibroids -Primary Endpoint has been Achieved -

2 News Release: September 17, 2024

Launch of YSELTY® (generic name linzagolix) for uterine fibroid treatment in Europe

3 News Release: December 23, 2024

Regarding the approval of the additional indication for endometriosis in Europe for the GnRH antagonist YSELTY® (generic name linzagolix)

«Reference»

About Linzagolix (KLH-2109)

Linzagolix is an orally administrable GnRH (gonadotropin-releasing hormone) antagonist. It competes with GnRH at the GnRH receptors in the pituitary gland, suppressing the secretion of gonadotropins, which are gonadal-stimulating hormones. By reducing the production of estrogen in the ovaries, it is expected to improve the symptoms of uterine fibroids and endometriosis.

Linzagolix (generic name), which was discovered by the Company and licensed out to Theramex (U.K.), was launched to the market in Germany in September 2024 under the product name Yselty® for the indication of uterine fibroids, followed by the launch and preparations for launch in other European countries. In Taiwan, an approval application has been submitted by Synmosa Biopharma Corporation (Taiwan), and in South Korea, JW Pharmaceutical Corporation (South Korea) is preparing for development.

In Japan, our company has submitted an approval application targeting uterine fibroids and is preparing for a Phase III clinical trial targeting endometriosis.

About Uterine Fibroids

Uterine fibroids is a benign tumor that develops in the smooth muscle that makes up the uterine myometrium and grows in a sex hormone-dependent manner. It has been reported that hypermenorrhea and chronic pain symptoms have a significant impact on patients' quality of life (QOL).