



December 22, 2025

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

Marketing Authorization Approval in Japan for Yselty® Tablets 100mg, an Oral GnRH Antagonist, Indicated for Uterine Fibroids

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced that it has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for its GnRH antagonist Yselty® Tablets 100 mg (generic name: Linzagolix choline), discovered and developed by Kissei, for the indication of uterine fibroids.

Yselty® is an orally administered GnRH (gonadotropin-releasing hormone) antagonist. Yselty® acts by antagonizing GnRH at the GnRH receptor in the pituitary gland and consequently suppressing the secretion of gonadotropins. Ultimately reducing the production of estrogen in the ovaries, and improving various symptoms of uterine fibroids.

We have conducted domestic Phase III clinical trials (KLH2301 and KLH2302) for uterine fibroids, and based on the results of these trials¹, we filed an application for manufacturing and marketing approval for this drug in February 2025². We are also conducting domestic Phase III clinical trials for endometriosis in Japan³.

Uterine fibroids are a disease that has been reported to affect more than 70% of women⁴. It is more common in women in their 30s and 40s, when they are in the prime of their working lives, and can seriously affect patients' quality of life (QOL) and social activities due to excessive menstrual periods and chronic pain symptoms. According to an estimate of economic losses due to women-specific health issues conducted by the Ministry of Economy, Trade and Industry in 2024, the total annual loss of labor productivity due to menstrual complications is estimated at approximately 570 billion yen⁵, and uterine fibroids are one of the causative diseases.

Kissei is preparing for the launch of Yselty® with the aim of providing a new treatment option for patients with uterine fibroids, thereby contributing to the creation of a society where women can thrive in good health.

There is no change to the consolidated financial results forecast for the fiscal year ending March 31, 2026.

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: February 26, 2025

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

3 News release: March 31, 2025

Kissei Initiates Phase III Clinical Trial for GnRH Antagonist "Linzagolix" Indicated for Endometriosis

4 Elizabeth A. Stewart, Shannon K. Laughlin-Tommaso, William H. Catherino, Sujata Lalitkumar, Devashana Gupta & Beverley Vollenhoven. Nature Reviews Disease Primers volume 2, Article number: 16043 (2016) <https://www.nature.com/articles/nrdp201643>

5 Ministry of Economy, Trade and Industry, "Estimation of Economic Losses Due to Women's Specific Health Issues and the Need for Health Management"

https://www.meti.go.jp/policy/mono_info_service/healthcare/downloadfiles/jyosei_keizaisonshitsu.pdf

<Reference>

Product Summary of Yselty® Tablets 100mg

Brand Name	Yselty® Tablets 100mg
Generic Name	Linzagolix choline
Indications	Improvement of the following symptoms based on uterine fibroids Excessive menstrual cycle, lower abdominal pain, back pain, anemia
Dosage and Administration	The usual adult dosage of Linzagolix is 200 mg orally once daily. The first dose should be administered on days 1-5 of the menstrual cycle
Formulation	Film coated tablets
Manufacturing and Marketing Authorization Holder	Kissei Pharmaceutical Co., Ltd.
Date of Marketing Approval in Japan	December 22, 2025

About Yselty® Tablets

Yselty® is an orally available GnRH (gonadotropin-releasing hormone) antagonist discovered and developed by the Company. Overseas, Theramex (U.K.), to which we licensed out the technology, launched the product under the brand name Yselty® in Germany in September 2024, and is subsequently preparing for the launch and launch in other European countries. In Taiwan, Synmonsa BioPharma (Taiwan) received marketing approval in October 2025 and is preparing for the launch. JW Pharma (South Korea) and Searchlight Pharma (Canada) are also developing the drug in South Korea and Canada, respectively.

About Uterine Fibroids

Uterine fibroids are benign tumors that develop in the smooth muscle of the uterine myometrium and grow in a sex hormone-dependent manner. The most common symptoms include excessive menstruation and associated anemia, lower abdominal pain, and back pain.