



October 23, 2025

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

Linzagolix Approved for Marketing in Taiwan

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; hereinafter "Kissei") is pleased to announce that Synmosa Biopharma Corporation (Taiwan; Head Office: Taiwan; CEO: Peter Lin; hereinafter "Synmosa"), which has licensed the development and marketing rights in Taiwan for Kissei's GnRH antagonist Linzagolix has received approval from the Taiwan Food and Drug Administration (TFDA) to market the agent under the brand name "Yselty[®]" for the treatment of uterine fibroids.

Linzagolix is an orally administered GnRH (gonadotropin-releasing hormone) antagonist. Linzagolix 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, it is expected to improve the symptoms of uterine fibroids and endometriosis. In November 2022, Kissei granted Synmosa the rights to develop and market Linzagolix in Taiwan¹

.In Japan, Kissei submitted a new drug application for the indication of uterine fibroids and is currently under regulatory review². Kissei is concurrently conducting a Phase III clinical trial for endometriosis³. In overseas, Theramex (UK) launched the product under the brand name "Yselty[®]" for the indication of uterine fibroids in Europe in September 2024⁴. Furthermore, in November of the same year, Theramex received approval from the European Medicines Agency (EMA) for the additional indication of endometriosis⁵. Development is also underway in South Korea and Canada through other partnering companies.

The obtaining of marketing approval is expected to provide a new treatment option for patients with uterine fibroids in Taiwan.

The impact on the earnings forecast has already been incorporated into the consolidated earnings forecast for the fiscal year ending March 31, 2026, which was announced on May 7th, 2025.

1 News Release: November 2, 2022

Licensing Agreement for GnRH Antagonist Linzagolix with Synmosa Biopharma Corporation in Taiwan

2 News Release: February 26, 2025

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

3 Press Release: March 31, 2025

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

4 News Release: September 17, 2024

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

5 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 Synmosa Biopharma Corporation

Synmosa Pharmaceuticals is a Taiwanese over-the-counter company (stock code: TW.4114) established in 1980. The company focuses on various therapeutic areas, including cardiovascular, respiratory, gynecology, urology, oncology, and central nervous system. It operates a sustainable business spanning research and development, manufacturing, contract manufacturing, sales, and distribution of pharmaceuticals and health foods.

For more information about Synmosa, please visit <https://www.synmosa.com.tw/en/home/Default.asp>