

July 30, 2021

**Notification of Transfer of Marketing Rights for ORAVI® Mucoadhesive Tablets 50mg
for Oropharyngeal Candidiasis**

Sosei Group Corporation (Headquarters: Chiyoda-ku, Tokyo, Japan; Chairman, President and CEO: Shinichi Tamura,) and Hisamitsu Pharmaceutical Co., Ltd. (Headquarters: Tosu city, Saga prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter "Hisamitsu Pharmaceutical"), and FUJIFILM Toyama Chemical Co., Ltd., (Headquarters: Chuo-ku, Tokyo, Japan; President : Junji Okada, hereinafter "FUJIFILM Toyama Chemical ") announce that the companies have agreed to transfer the distribution operation of ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis, of which Sosei Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo, Japan; Representative Director & President: Tadayoshi Yasui, hereinafter "Sosei"), a wholly-owned subsidiary of Sosei Group Corporation, obtained manufacturing and marketing authorization in Japan, from FUJIFILM Toyama Chemical to Hisamitsu Pharmaceutical. The transfer of the distribution is planned to be implemented on November 1, 2021.

This product is a new dosage form of “Japanese pharmacopoeia miconazole” for the treatment of oropharyngeal candidiasis. The formulation is a mucoadhesive tablet designed to release the active ingredient to mouth cavity for sustained period of time and continually by attaching the tablet to the upper jaw gum.

Sosei obtained the manufacturing and marketing approval on this product in 2018 and FUJIFILM Toyama Chemical has distributed this product since 2019. Hisamitsu Pharmaceutical will distribute this product and conduct medical information activities in Japan on execution of this transfer.

This material is an English translation of the press release announced on July 30, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Reference

ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis

This product was developed by French company, BioAlliance Pharma SA and transferred to French company, Vectans Pharma in July 2017 and the company is marketing the product. Marketing authorization (MA) on the product was granted in October 2006 under a tradename, Loramyc®, in France and countries in which its MAs have been granted as of April 2021 are 4 countries in Europe, the United States (tradename: Oravig®) and China (tradename: Oravig®). The product is currently being sold in France, Italy and the United States. In Japan, Sosei obtained manufacturing and marketing approval in 2018 and the product has been sold since February 2019.

Indication

Oropharyngeal candidiasis by genus candida

Dosage and Administration

The usual recommended dose for an adult is one table (miconazole 50mg) once daily by attaching the table to the upper jaw gum (canine fossa)

Manufacturing and marketing authorization and sales of ORAVI® Mucoadhesive Tablets 50mg

	Until October 31, 2021	On and after November 1, 2021
Manufacturing and marketing approval	Sosei Co., Ltd.	Sosei Co., Ltd. (No change)
Sales	FUJIFILM Toyama Chemical Co., Ltd.	Hisamitsu Pharmaceutical Co., Inc.