



Sosei Announces Approval of ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis in Japan

Tokyo, Japan and London, UK, 25 September 2018 – Sosei Group Corporation (“Sosei” or the “Company”; TSE Mothers Index: 4565) announces that its wholly-owned Japanese subsidiary Sosei Co., Ltd., has received the approval in Japan for ORAVI® Mucoadhesive Tablets 50mg.

ORAVI® (Investigational Code SO-1105) is a novel formulation of the Japanese pharmacopeia miconazole (antifungal agent), the once-daily treatment mucoadhesive tablet to treat oropharyngeal candidiasis (“OPC”) in patients. Lauriad™, the proprietary technology is applied for ORAVI® to extendedly deliver high concentration of miconazole level directly in infected site of mouth.

Sosei Co. Ltd has granted an exclusive license to Fujifilm Group for the commercialization of ORAVI® in Japan. Sosei will receive a milestone payment of JPY 200 million (approximately USD 1.78 million equivalent) from the company for approval and is entitled to receive royalties on sales in Japan, plus additional payments based on the achievement of further sales-based milestones.

ORAVI® was developed by the French pharmaceutical company BioAlliance Pharma SA. and was first approved in October 2006 in France. It has since been marketed in 2 European countries and the United States, under the tradenames Loramyc®/Oravig®.

Sosei Co. Ltd. obtained the exclusive marketing rights for ORAVI® in Japan from BioAlliance Pharma SA. in May 2011. The New Drug Application for ORAVI® in Japan included data from the original clinical trials and from an additional randomized Phase 3 clinical trial, conducted by Sosei Co. Ltd in Japan that confirmed the safety and efficacy of ORAVI® to be equivalent to an approved formulation of miconazole in OPC patients.

Tadayoshi Yasui, representative Director & President of Sosei Co., Ltd., said: “We are pleased to receive this approval for ORAVI® in Japan, which now paves the way forward for its launch in the coming months. We are grateful to the clinical investigators, hospital staff and patients who made this approval possible through their participation in our clinical development program. We are confident that ORAVI®, which is planned to be sold through our partner FUJIFILM has the potential to become a successful new treatment for patients.”

The effect of the approval on our outlook for the accounting period ending December 2018 is expected to be minor.

- Ends -

Notes

Outline of ORAVI® Mucoadhesive Tablets 50mg

[Approval date]	21 September 2018
[Market Authorization Holder]	Sosei Co., Ltd.
[Product name]	ORAVI® Mucoadhesive Tablets 50mg
[Content/Description]	Miconazole 50mg per Tablet

Oropharyngeal candidiasis [1, 2]

Oropharyngeal candidiasis is a fungal infection caused mainly by *Candida albicans*. It occurs most frequently in patients who are immunocompromised due to HIV, malignant tumors, etc. There are various clinical forms of oropharyngeal candidiasis including pseudomembranous candidiasis, and erythematous (atrophic) candidiasis. Symptoms include tongue pain, burning sensation, dysgeusia, and dysphagia, and signs include white moss, erythema, and angular cheilitis. With the aging population, and improvements in medical techniques, the prevalence of candidiasis is increasing.

1. Hideyo Yamaguchi: Pathogenic Fungi and Fungal Diseases (rev. ed. 4), Nankodo, Tokyo, 2007, pp. 238-239.
2. Committee for Establishing Guidelines for Oral Candidiasis Pharmacotherapy, Japanese Society of Oral Therapeutics and Pharmacology (ed.): Guidelines for Oral Candidiasis Pharmacotherapy: Fundamentals and Clinical Practice for Medical Treatment and Care (ed. 1), Ishiyaku Publishers, 2016, pp. 1-5.

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Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development and commercialization of products. Various risks may cause Sosei's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to



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market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.