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PRESS RELEASE

## Sosei Heptares to Launch ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis in Japan

Tokyo, Japan and London, UK, 31 January 2019 – Sosei Group Corporation (“the Company”; TSE: 4565), announces its wholly-owned Japanese subsidiary Sosei Co., Ltd. (“the Business”), will launch ORAVI® Mucoadhesive Tablets 50mg in Japan on 4 February 2019.

ORAVI® is a novel once-daily mucoadhesive tablet formulation of the antifungal agent miconazole for the treatment of oropharyngeal candidiasis (“OPC”), a condition that occurs frequently in immunocompromised patients. ORAVI® has been designed to deliver a sustained therapeutic concentration of miconazole directly in the mouth.

The Business received marketing approval in Japan for ORAVI® Mucoadhesive Tablets 50mg on 21 September 2018, after having gained the exclusive marketing rights for ORAVI® in Japan from the French pharmaceutical company BioAlliance Pharma SA in May 2011. ORAVI® was first approved in October 2006 in France. It is currently marketed in two European countries and the United States under the trade names Loramyc®/Oravig®.

Sosei Co., Ltd. has granted an exclusive license to FUJIFILM Toyama Chemical Co., Ltd. for the commercialization of ORAVI® in Japan. The Business is entitled to receive royalties on sales in Japan from FUJIFILM Toyama Chemical, plus additional payments based on the achievement of further sales-based milestones.

**Tadayoshi Yasui, Representative Director & President of Sosei Co., Ltd., said:** “We are pleased to announce the launch of ORAVI® in Japan. We are confident that ORAVI® has the potential to become a successful new treatment for patients suffering with OPC by making use of its locally administered and sustained-release characteristics to maximize the efficacy of miconazole. ORAVI® will be sold by FUJIFILM Toyama Chemical, and we look forward to working with them to support the commercialization of ORAVI® and to contribute to improving the health and quality of life for patients.”

The effect of the launch on our outlook for the accounting period ending December 2019 is expected to be minor.

– Ends –

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Notes

**Outline of the Product**

Mucoadhesive tablet to treat oropharyngeal candidiasis

[Product name] ORAVI® Mucoadhesive Tablets 50mg

[Indication] Oropharyngeal candidiasis by genus candida

[Dosage/Administration] The usual recommended dose for an adult is one tablet (miconazole 50mg) once daily by attaching the tablet to the upper jaw gum (canine fossa)



**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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### About Sosei Heptares

We are an international biopharmaceutical group focused on the design and development of new medicines originating from its proprietary GPCR-targeted StaR<sup>®</sup> technology and structure-based drug design platform capabilities. The Company is advancing a broad and deep pipeline of partnered and wholly owned product candidates in multiple therapeutic areas, including CNS, immuno-oncology, gastroenterology, inflammation and other rare/specialty indications. Its leading clinical programs include partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and next generation immuno-oncology approaches to treat cancer (with AstraZeneca). Our additional partners and collaborators include Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab and MorphoSys. The Company is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK and Zurich, Switzerland.

"Sosei Heptares" is the corporate brand of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit <https://www.oseiheptares.com/>

LinkedIn: [@oseiheptaresco](#) | Twitter: [@oseiheptaresco](#)

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### About FUJIFILM Toyama Chemical Co., Ltd.

FUJIFILM Toyama Chemical was launched by merging FUJIFILM RI Pharma Co., Ltd., a company that conducts the research, development, manufacture, and sales of radiopharmaceuticals, and TOYAMA CHEMICAL CO., LTD., a company that conducts the research, development, manufacture, and sales of small molecule pharmaceutical products. FUJIFILM Toyama Chemical dedicates efforts to developing innovative diagnostic and therapeutic radiopharmaceuticals and therapeutic drugs with unique mechanisms of action in the fields of "oncology", "central nervous system diseases", and "infectious diseases" where significant unmet medical needs still exist, with close collaboration with FUJIFILM Corporation which focuses on research of new medicines. It will also advance the development of new medicines utilizing drug delivery system (DDS) technologies that timely deliver the required amount of a drug to the specific body area. Also, by exploring synergy with in vitro diagnostic (IVD) devices and reagents owned by Fujifilm group companies, the company will expand its offering of comprehensive solutions from "diagnosis" to "treatment".

For more information of FUJIFILM Toyama Chemical, please visit <http://fftc.fujifilm.co.jp/en/>

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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 Group Corporation'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 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.