



## **Sosei announces submission of marketing authorization application of SO-1105 for oropharyngeal candidiasis**

**Tokyo, Japan – 28 February 2017:** Sosei Group Corporation (TSE Mothers Index: 4565) hereby announces that its Japanese subsidiary Sosei Co. Ltd. has submitted a New Drug Application for the marketing in Japan of SO-1105 (miconazole 50 mg, muco-adhesive tablet) for the treatment of oropharyngeal candidiasis yesterday.

SO-1105 is a novel formulation of the antifungal agent miconazole, administered for the first time in Japan as a once-daily muco-adhesive tablet for the treatment of oropharyngeal candidiasis in the patients such as immunocompromised. It has the potential to offer a new treatment option, as release of the active component is local and sustained thereby increasing the convenience for patients.

Loramyc® (SO-1105 in Japan) was developed by Onxeo SA (referred to hereafter as “Onxeo”), formerly known as BioAlliance Pharma SA. The product is commercialized in the US under the name of Oravig® and in Europe under the name of Loramyc®. The proprietary technology used for SO-1105 development, called Lauriad™, has been developed to provide high concentrations of the active ingredient directly at the site of infection. Sosei Co. Ltd. obtained the exclusive marketing rights for SO-1105 in Japan from Onxeo in May 2011 and has already entered into an exclusive contract for marketing and commercialization with Fujifilm Pharma Co., Ltd.

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### **Notes to Editors**

#### **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 frequency of candidiasis is increasing.

#### **About Sosei**

Sosei Group Corporation is an international biopharmaceutical company originating from Japan that discovers and develops innovative biopharmaceuticals for the treatment of Alzheimer's disease, schizophrenia, cancer, migraine, addiction, metabolic disease, and other indications. By utilizing its GPCR structure-based drug design platform technology, Sosei have established a product pipeline with first/best in class potential. Through development and commercialization partnerships, Sosei have already delivered two bronchodilators for COPD which generate significant and stable revenue streams that enable further growth. Sosei partners include Novartis, Allergan, AstraZeneca,

MedImmune, MorphoSys, Teva, and Pfizer and we are actively looking for new partnerships to enhance the development of our products and help us deliver them to patients worldwide.

For further information about Sosei, please visit <http://www.osei.com/en/>.

### **About Onxeo**

Onxeo is a clinical-stage biotechnology company developing innovative drugs for the treatment of orphan diseases in oncology, driven by high therapeutic demand in one of the fastest growing segments of the pharmaceutical industry.

Onxeo's objective is to become a major international player in the field of rare cancers. Its growth strategy is founded on the development of innovative, effective, and safe drugs based on breakthrough technologies that can make a real difference in the treatment of orphan oncology diseases and considerably improve the quality of life of patients affected by rare or resistant cancers. Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with 3 major products in several on-going preclinical and clinical programs, alone or in combination, for multiple cancer indications.

The Company is headquartered in Paris, France with offices in Copenhagen and in New York, and has approximately 60 employees. Onxeo is listed on Euronext in Paris, France (Ticker: ONXEO, ISIN Code: FR0010095596) and Nasdaq Copenhagen, Denmark (Ticker: ONXEO).

Learn more by visiting [www.onxeo.com](http://www.onxeo.com)

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.