

**Santen Announces Approval of Ikervis  
for EU Marketing Authorization**

March 25, 2015 , Osaka, Japan – Santen Pharmaceutical Co., Ltd. today announced it received approval of the Marketing Authorization Application (MAA) for Ikervis from the European Commission (EC). Ikervis is approved for treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.

The MAA approval was supported by a phase III clinical program investigating the efficacy and safety of ciclosporin in European dry eye disease patients with severe keratitis. Based on quality, safety and efficacy data submitted, Ikervis had received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency in January, 2015. The CHMP considered that there was a favorable benefit-to-risk balance for Ikervis and therefore recommended the granting of the marketing authorization. Ikervis is the first drug for the treatment of severe keratitis in adult patients with dry eye disease in Europe.

Professor Andrea Leonardi, University of Padua, Italy, added: "The treatment of severe keratitis in dry eye patients so far represented a real therapeutic challenge and the availability of Ikervis in Europe will represent a significant progress in the management of severe dry eye patients."

Masamichi Sato, Head of Santen Europe and President of Santen Holdings EU B.V., concluded: "We are delighted with today's MAA approval that offers dry eye disease patients with severe keratitis the first prescription treatment in Europe. Our commitment is to continue to deliver new treatments for people suffering from dry eye. Ikervis is a tangible result of Santen's patient-centered approach to innovation."

### **About Ikervis**

The active substance of Ikervis is ciclosporin, an immunosuppressive agent, belonging to the therapeutic class of ophthalmic products. Ciclosporin blocks the release of pro-inflammatory cytokines and exerts an anti-inflammatory effect in ocular surface cells. The benefits with Ikervis are its ability to improve ocular surface damage and reduce inflammation in dry eye disease patients with severe keratitis.

### **About Santen**

As a specialty company dedicated to the ophthalmic and anti-rheumatic fields, Santen carries out the research, development, sales, and marketing of pharmaceuticals. The company has its bases in about 20 countries and delivers products in more than 70 countries. In Japan, Santen holds the No. 1 share in the prescription ophthalmic pharmaceutical market. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs.

### **Santen Forward-looking Statements**

Information provided in this press release contains so-called “Forward-looking Statements”. The realizations of these forecasts are subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial condition are subject to the effects of change in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

*This press release is also prepared in other languages. However this English document is the original document, and documents prepared in other languages are for your reference only. In case of any discrepancy between the English and translated versions, the English version will prevail. Please refer to <http://www.santen.com> for the original English document.*

### **Contact**

#### **Takashi Hibi**

General Manager

Corporate Communication Group

Santen Pharmaceutical Co., Ltd.

E-mail: [ir@santen.co.jp](mailto:ir@santen.co.jp)

Tel: +81-6-4802-9360