

**Santen receives a Positive CHMP Opinion for EU Marketing  
Authorization for Ikervis®**

January 23, 2015 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced that Santen S.A.S., its subsidiary in France, received a positive opinion recommending the granting of a marketing authorization for Ikervis®, from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

Santen submitted a Marketing Authorization Application (MAA) under the centralized procedure for Ikervis® in December 2013. The CHMP based its positive opinion on its review of the comprehensive data package for Ikervis®. Ikervis® was granted a positive opinion for the “treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes”.

The active substance of Ikervis® is ciclosporin, an immunosuppressant, 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 15 bases in 12 countries globally and delivers products to consumers 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