

Santen Launches Ikervis in Germany

July 15, 2015 , Osaka, Japan – Santen Pharmaceutical Co., Ltd. announced the launch of Ikervis for treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes, in Germany. Ikervis will be launched sequentially in Europe.

The Marketing Authorization Application (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 an approval of the MAA for Ikervis from the European Commission (EC) in March 2015. Ikervis is the first drug for the treatment of severe keratitis in adult patients with dry eye disease in Europe.

Shigeo Taniuchi, Head of Santen Europe and President of Santen Holdings EU B.V., commented: "We are really excited to launch Ikervis in Germany. Ikervis is a tangible result of Santen's patient-oriented approach to innovation as well as strong collaboration with researchers in the world. We are pleased that Ikervis is now available for patients who face challenges from severe keratitis with dry eye, and hoping to launch in other European countries in the soonest manner in order to contribute people suffering from dry eye in Europe."

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 field, Santen carries out 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.

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Contact

Takashi Hibi

General Manager

Corporate Communication Group

Santen Pharmaceutical Co., Ltd.

E-mail: ir@santen.co.jp

Tel: +81-6-4802-9360