

# News Release



## Santen Announces Approval of *TAPROS* for the Treatment of Open-Angle Glaucoma and Ocular Hypertension in China

August 25, 2015, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) announced today that it received an import drug license of *TAPROS Ophthalmic Solution 0.0015%* (generic name: tafluprost; hereinafter “*TAPROS*”) for the treatment of open-angle glaucoma and ocular hypertension in China on July 27, 2015 with required procedures completed on August 21<sup>st</sup>.

*TAPROS* is the Prostaglandin F<sub>2a</sub> Analogue co-developed by Santen and Asahi Glass Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo) for the reduction of intraocular pressure (IOP) in glaucoma and ocular hypertension. Santen conducted pharmaceutical, nonclinical and clinical development for *TAPROS*, while Asahi Glass conducted the active pharmaceutical ingredient development. In Japan, *TAPROS* has been sold since December 2008 as *TAPROS Ophthalmic Solution 0.0015%*, and is expanded over 60 countries at this time.

Glaucoma is a disease characterized by optic nerve disorder and progressive visual field defects due to increased intraocular pressure or other factors. Glaucoma is known as one of the leading causes of visual impairment (low vision and blindness). Because the optic nerve disorder and visual field disorder caused by glaucoma are essentially progressive and irreversible, early detection and treatment is required, and treatment of glaucoma is usually intended to lower intraocular pressure.

Santen has sold several kinds of ophthalmic solutions in such as the corneal and conjunctival disease area and the bacterial conjunctivitis area in China. The addition of *TAPROS* to Santen’s product lineup can be a useful treatment option allowing Santen to further contribute to improvement in patient quality of life.

Santen has no plans to revise its full-year financial forecasts because of the approval of *TAPROS*.

### About *TAPROS* in China

Generic name: Tafluprost

Dosage form: Aqueous ophthalmic solution

Indication: Open-angle glaucoma and ocular hypertension  
Dosage: 1 drop/time, once daily

#### Product Characteristics

- *TAPROS* is a type of prostaglandin F<sub>2α</sub> analogue, which is often used treatment for glaucoma and ocular hypertension.
- *TAPROS* increases uveoscleral outflow of the aqueous humor, and shows a potent and stable IOP-lowering effect.
- *TAPROS* has been confirmed to have a reliable IOP-lowering effect in normal tension glaucoma.
- *TAPROS* has been indicated to increase retinal arterial blood flow around the optic nerve head, as well as increasing the blood flow in the retinal tissue.
- No serious ocular or systemic adverse events have been found.
- Shelf life of the product is for 3 years under room temperature (from 1 to 30°C).

#### **About Santen**

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, sales, and marketing of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in over 50 countries. 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. For more details, please see Santen's website ([www.santen.com](http://www.santen.com)).

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

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is 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 conditions are subject to the effects of changes 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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