

Santen Announces Approval of TAPROS™ for Glaucoma and Ocular Hypertension Treatment in Japan

October 17, 2008 Osaka Japan-- Santen Pharmaceutical Co., Ltd. today has announced that MHLW of Japan granted approval for its new glaucoma and ocular hypertension treatment drug, "TAPROS Ophthalmic Solution 0.0015%" (Generic name: tafluprost) on October 16, 2008.

"TAPROS Ophthalmic Solution 0.0015%" is the first Prostaglandin Analogue developed in Japan for the reduction of intraocular pressure (IOP) in glaucoma and ocular hypertension. The drug was co-developed by Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo). Santen conducted pharmaceutical, nonclinical and clinical development, while Asahi Glass manufactured the active pharmaceutical ingredient. In Japanese clinical trials, the drug showed potent and stable IOP-lowering effects. In addition, it is the first drug in which the submission package includes the data of prospective and randomized clinical trial to evaluate efficacy in normal tension glaucoma patients.

Glaucoma is a disease in which the optic nerve is damaged by IOP elevation, etc., causing progressive visual field loss, if left untreated it may lead to blindness. It is a major cause of visual disturbance (visual acuity loss, blindness) by ocular disease. Glaucomatous optic nerve damage and visual field loss is progressive and irreversible in general, early detection and early treatment of glaucoma is essential. The basic treatment for glaucoma is IOP lowering as well as IOP control. This also applies to normal tension glaucoma, which is seen frequently in Japanese Glaucoma patients.

Santen Pharmaceutical Co., Ltd. already has several glaucoma treatment drugs on the market, and the addition of "TAPROS Ophthalmic Solution 0.0015%" in the Santen product lineup is expected to enhance treatment choices for medical care givers, and contribute to improve the patients' QOL (quality of life).

About Tafluprost

Product Name:	TAPROS Ophthalmic Solution 0.0015%
Generic name:	Tafluprost
Dosage form:	Aqueous ophthalmic solution
Indication:	Glaucoma and ocular hypertension
Dosage:	1 drop/time, once daily
Storage method	Can be stored at room temperature

Product Characteristics:

- TAPROS is a type of prostaglandin F_{2α} analogue, which is currently the most frequently used first-line 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, a disease seen in a high ratio of the Japanese Glaucoma population.
- TAPROS has been indicated to increase retinal arterial blood flow around the optic disk, as well as increasing the blood flow in the retinal tissue.
- No serious ocular or systemic adverse events have been found.
- The formulation remains stable under room temperature for 3 years.