

Santen Announced Approval for TAPCOM Combination Ophthalmic Solution for the Treatment of Glaucoma and Ocular Hypertension

September 20, 2013, Osaka Japan---Santen Pharmaceutical Co., Ltd. announced to receive approval from the Japanese Ministry of Health, Labor and Welfare for the manufacture and sales of TAPCOM Combination Ophthalmic Solution (generic name: tafluprost/timolol maleate: hereafter “TAPCOM”) for the treatment of glaucoma and ocular hypertension.

TAPCOM contains both timolol maleate and tafluprost. Tafluprost is the active ingredient in TAPROS Ophthalmic Solution 0.0015%, an original glaucoma and ocular hypertension treatment co-developed by Santen and Asahi Glass Co., Ltd. (Tokyo) and launched in 2008.

Glaucoma is a disorder characterized by optic nerve damage and progressive visual field loss resulting from abnormally elevated intraocular pressure (IOP). The disease is a major cause of visual impairments such as vision loss; left untreated, it may even lead to blindness. Because glaucomatous nerve damage and visual field loss is generally considered to be irreversible, therapy primarily focuses on reduction and control of IOP over an extended period of time.

Glaucoma treatment often involves the administration of multiple IOP-lowering medications. In other words, a combination of two or more types of drugs is more effective in controlling IOP than a single compound. However, therapy with multiple drugs requires frequent doses and complicated dosing schedules, making it difficult for patients to properly manage to their treatment regimen. TAPCOM is advantageous in this regard because it features two types of IOP-lowering compounds in a single formulation. Tafluprost is a prostaglandin F_{2α} analogue that promotes the outflow of aqueous humor, the accumulation of aqueous humor leads to high IOP, and timolol is a β blocker that inhibits the production of aqueous humor.

The approval of TAPCOM allows Santen to expand our current lineup of advanced pharmaceuticals, which includes monotherapies such as TAPROS Ophthalmic Solution 0.0015%. We are confident the launch of TAPCOM will benefit our efforts to improve the quality of life of patients everywhere by giving health care professionals a wider range of treatment options.

<Product Outline>

Product Name:	TAPCOM Combination Ophthalmic Solution
Generic name:	Tafluprost/timolol maleate
Formulation:	Aqueous ophthalmic solution
Indications:	Glaucoma, ocular hypertension
Dosage:	One drop at a time, once daily
Storage :	Store at room temperature away from light in a sealed container

Forward-looking Statements

Information provided in this press release contains so-called “forward looking statements”. The realization 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 conditions are subject to the effects of changes in regulations made by governments in Japan and other nations concerning medical system, drug pricing and other systems, as well as fluctuations in market variables such as interest and foreign exchange rates.