

News Release



Santen Announces Approval of Glaucoma and Ocular Hypertension Therapeutic, COSOPT Mini Ophthalmic Solution in Japan

Osaka, Japan, March 12, 2015—Santen Pharmaceutical Co., Ltd. (hereafter “Santen”) announced that it has received approval from the Japan Ministry of Health, Labour and Welfare (MHLW) for the manufacture and sales of COSOPT Mini Combination Ophthalmic Solution (generic name: dorzolamide hydrochloride/timolol maleate; hereafter “COSOPT Mini”) for the glaucoma and ocular hypertension as of March 10, 2015.

COSOPT Mini is a preservative-free solution in single-dose disposable containers, which contains the same active ingredients as COSOPT Combination Ophthalmic Solution which contains TRUSOPT Ophthalmic Solution 1% (generic name: dorzolamide hydrochloride) and TIMOPTOL Ophthalmic Solution 0.5% (generic name: timolol maleate).

In Japan, MSD K.K. (headquartered in Tokyo, Japan), which is a subsidiary of Merck & Co., Inc., headquartered at Whitehouse Station, NJ., U.S.A. (hereafter “Merck USA”), gained approval for manufacturing and marketing of COSOPT Combination Ophthalmic Solution (hereafter “COSOPT”) as of April, 2010. Since June, 2010, it had been marketed by Santen, under a copromotion arrangement between the two companies. In August 2014, the manufacturing and marketing right was transferred from Merck to Santen.

Glaucoma is a disease characterized by optic nerve disorder and progressive visual field defect due to increased intraocular pressure or other factors. Glaucoma is known as one of the leading causes of visual impairment (decreased visual acuity and blindness). Because the optic nerve disorder and visual field disorder caused by glaucoma are essentially progressive and irreversible, its treatment is usually

intended to lower and long control intraocular pressure. As a chronic disease, glaucoma requires a long time of treatment. Accordingly, patients who are hypersensitive to benzalkonium chloride (BAK) or any other preservative and those with severe conjunctival epithelial disorder are in need of preservative-free formulations.

This approval of preservative-free formulation COSOPT Mini will benefit Santen's efforts to improve the quality of life of patients by giving health care professionals a wider range of treatment options.

About COSOPT Mini

Generic Name:	Dorzolamide hydrochloride/ timolol maleate
Formulation:	Aqueous ophthalmic solution
Indications	In case treatment with other glaucoma drugs is insufficient in patients with the following disease: glaucoma, ocular hypertension <Precautions Related to Indications and Use> Monotherapy treatment should be prioritized.
Dosage	One drop instilled twice daily

Product Characteristics:

- COSOPT Mini is a combination ophthalmic solution containing TRUSOPT Ophthalmic Solution 1% (generic name: dorzolamide hydrochloride), and TIMOPTOL Ophthalmic Solution 0.5% (generic name: timolol maleate)
- COSOPT Mini contains the same active ingredient and concentration as COSOPT Combination Ophthalmic Solution
- COSOPT Mini is packaged in single-dose disposable containers

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.

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