

Santen Files for Manufacturing/Marketing Approval of its Glaucoma and Ocular Hypertension Therapeutic, *COSOPT Mini Combination Ophthalmic Solution*

Osaka, Japan, August 15, 2014—Santen Pharmaceutical Co., Ltd. (Osaka; hereafter “Santen”) announced today that it filed an application for approval of manufacturing and marketing of the glaucoma and ocular hypertension therapeutic *COSOPT Mini Combination Ophthalmic Solution* (generic name: dorzolamide hydrochloride/ timolol maleate; hereafter “*COSOPT Mini*”) in Japan as of August 15, 2014.

COSOPT Mini is a combination ophthalmic solution containing *TRUSOPT Ophthalmic Solution 1%* (generic name: dorzolamide hydrochloride), a carbonic anhydrase inhibitor (CAI), and *TIMOPTOL Ophthalmic Solution 0.5%* (generic name: timolol maleate), a β blocker, and a preservative-free formulation based on *COSOPT Combination Ophthalmic Solution*. *COSOPT Combination Ophthalmic Solution* was developed by Merck & Co., Inc., (headquartered at Whitehouse Station, NJ., U.S.A., hereafter “Merck”; MSD outside the U.S.A. and Canada), and since its approval in Mexico in 1998, it has been marketed in about 90 countries, including the U.S.A. Currently, it is the most widely used combination ophthalmic solution for the treatment of glaucoma and ocular hypertension in the world.

* Outside Japan, the active ingredient concentrations are 2% dorzolamide hydrochloride and 0.5% timolol maleate.

In Japan, clinical studies of a combination of 1% dorzolamide hydrochloride and 0.5% timolol maleate were conducted on the basis of extensive data from Merck. In April 2010, MSD K.K. (Merck’s subsidiary headquartered in Tokyo, Japan) gained approval for its manufacturing and marketing. Since June of the same year, it had been marketed by Santen, with product detailing implemented cooperatively by the two companies. In August 2014, the manufacturing and marketing approval was transferred from Merck to Santen, and since then, both marketing and product detailing for the product have been carried out by Santen.

Glaucoma is a disease characterized by optic nerve disorder and progressive visual field defect due to increased intraocular pressure or other factors. If left untreated and in the worst case, it can result in blindness. As such, glaucoma is 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.

Having acquired manufacturing and marketing approval for the preservative-free formulation *COSOPT Mini Combination Ophthalmic Solution*, Santen hopes to be able to offer a broader range of treatment options for glaucoma to clinical settings, thus helping improve quality of life for patients.

<About *COSOPT Mini Combination Ophthalmic Solution* >

Generic Name:	Dorzolamide hydrochloride/ timolol maleate
Formulation:	Aqueous ophthalmic solution
Indications	Glaucoma and ocular hypertension
Dosage	The usual dosage is one drop instilled twice daily