



Santen Pharmaceutical Co., Ltd.

## **Banyu and Santen Launch “COSOPT<sup>®</sup> Combination Ophthalmic Solution”: Glaucoma and Ocular Hypertension Drug**

(<sup>®</sup>: Registered Trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.)

June 11, 2010-- Santen Pharmaceutical Co., Ltd. (Osaka, Japan, Akira Kurokawa, President and CEO; hereafter “Santen”) and Banyu Pharmaceutical Co., Ltd. (Tokyo, Japan, Mark Timney; President and Representative Director; hereafter “Banyu”) announced today that they have launched the glaucoma and ocular hypertension treatment drug “COSOPT<sup>®</sup> Combination Ophthalmic Solution” (generic name: dorzolamide hydrochloride-timolol maleate; hereafter “COSOPT<sup>®</sup>”), following its listing in the National Health Insurance Price list.

COSOPT<sup>®</sup> is a combination ophthalmic solution which contains TRUSOPT<sup>®</sup> Ophthalmic Solution 1% (generic name: dorzolamide hydrochloride), a carbonic anhydrase inhibitor (CAI) and TIMOPTOL<sup>®</sup> Ophthalmic Solution 0.5% (generic name: timolol maleate), a beta-adrenergic receptor blocking agent. COSOPT<sup>®</sup> was developed by Merck & Co., Inc., Whitehouse Station, N.J., U.S.A., and since its initial approval in Mexico in 1998, it has been marketed in about 90 countries including the U.S.A. \* Now it is the most widely used combination ophthalmic solution for treatment of glaucoma and ocular hypertension in the world.

\* Outside Japan, the concentration of the combination is dorzolamide hydrochloride at 2%, and timolol maleate at 0.5%.

In Japan, Banyu developed COSOPT<sup>®</sup> and obtained manufacturing and marketing approval from Japanese Ministry of Health, Labour and Welfare (MHLW) on April 16, 2010. Pursuant to the Co-promotion Agreement, entered between Santen and Banyu on March 2, 2010, Santen will market the product, and promotion activities will be conducted by collaboration of Santen and Banyu.

### **Main Characteristics of COSOPT<sup>®</sup>**

- A combination ophthalmic solution of dorzolamide hydrochloride 1% and timolol maleate 0.5%
- Superior IOP-lowering effect

Clinical study results in Japan showed its effect to be significantly superior to TIMOPTOL<sup>®</sup> monotherapy, and equivalent to concomitantly use of TIMOPTOL<sup>®</sup> and TRUSOPT<sup>®</sup>.

- Effect of timolol is fully exerted.

The effect of timolol is fully exerted by twice daily topical instillation.

- Well tolerated.

In clinical studies in Japan, no new adverse drug reactions with combination ophthalmic solution were observed.

Glaucoma is a disorder which, if left untreated and in the worst case, can result in blindness. It is one of the leading causes of visual impairment (decreased visual acuity and blindness). Because optic nerve damage and visual field damage caused by glaucoma are essentially progressive and irreversible, early detection and early treatment is of paramount importance. Banyu and Santen will strive to contribute to glaucoma/ocular hypertension treatment in Japan through promotion of COSOPT<sup>®</sup>.

## < Cosopt® Product Summary >

Brand Name	Cosopt® Combination Ophthalmic Solution
Dosage Form	Ophthalmic Solution
Active Ingredients	Dorzolamide hydrochloride- timolol maleate (Japanese Pharmacopoeia)
Indications and Use	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 Administration	Topical instillation, one drop at a time, twice daily
Volume	5mL per bottle
Content	In 1mL, 10mg/ 50mg of dorzolamide/ timolol
Packaging	10 bottles per carton
Description	Clear, colorless, slightly viscous sterile ophthalmic solution
NHI drug price	668 JPY per 1mL

### **About Santen**

As a unique pharmaceutical company specializing in ophthalmic and anti-rheumatic/ bone and joint disease field, Santen contributes to maintaining people's eyesight and health. We apply our efforts in certain areas of expertise, mainly ophthalmology, in order to contribute to (the quality of life of) the patient and their loved ones, and society as a whole. For details please access: <http://www.santen.com/>

### **About Banyu**

Banyu Pharmaceutical Co. Ltd. is a subsidiary of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A., a global research-driven pharmaceutical company. Banyu lives on a belief that medicine is for the people and develops, manufactures and markets world-class medicines and vaccines that improve quality of life. For details, please access <http://www.banyu.co.jp/>.

### **About Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.**

Today's Merck is working to help the world be well. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching programs that donate and deliver our products to the people who need them. Merck. Be Well. For more information, visit [www.merck.com](http://www.merck.com).

**Note on Forward-looking Statements for Santen**

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 in 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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