News Release

Santen Announces Approval of DIQUAS™ for Dry Eye Treatment in Japan

April 16, 2010 Osaka, Japan---Santen Pharmaceutical Co., Ltd. announced today that the Japanese Ministry of Health, Labour and Welfare granted approval for its new dry eye treatment drug, DIQUAS Ophthalmic Solution 3% (generic name: diquafosol sodium) on April 16, 2010.

Diquafosol was licensed for certain ophthalmic uses from Inspire Pharmaceuticals, Inc. (U.S.A) and DIQUAS Ophthalmic Solution 3% was developed by Santen as a treatment for dry eye. Dry eye is a chronic disorder of the keratoconjunctival epithelium and tear film caused by various factors, and is accompanied by symptoms such as ocular discomfort and visual function disorder. In clinical studies conducted in Japan, DIQUAS Ophthalmic Solution 3% was shown to improve dry eye symptoms by promoting secretion of mucin and water, thereby bringing the tear film closer to a normal state. In addition, no serious ocular or systemic adverse drug reactions were found during the clinical trials.

Dry eye begins with symptoms of ocular discomfort such as burning, stinging or a foreign body sensation. However, when aggravated, the disease can become so serious that it interferes with everyday activities. Recently, studies have shown that the number of dry eye patients is increasing due to environmental pollution, increased visual activities (computer work, etc.), dry air in a room due to air conditioning, increased prevalence of contact lens wear, and in LASIK (laser assisted in-situ keratomileusis) refractive surgery. Currently, sodium hyaluronate ophthalmic solution and artificial tears are the primary products used for the treatment of dry eye syndrome in Japan.

Santen currently markets “Hyalein Ophthalmic Solution 0.1%” and several other dry eye treatment products. The addition of “DIQUAS Ophthalmic Solution 3%” to the Santen product lineup is expected to increase treatment choices for medical professionals, and contribute to improving QOL (quality of life) for dry eye patients.

About DIQUAS

Product name	DIQUAS Ophthalmic Solution 3%
Generic name (JAN)	Diquafosol tetrasodium
Dosage form	Aqueous ophthalmic solution
Indication	Dry eye
Dose method	Usually, 1drop at a time, 6 times a day
Storage method	Can be stored at room temperature

Product Characteristics

- DIQUAS is the first approved $P2Y_2$ receptor agonist in the world to be formulated as ophthalmic solution, and has a new mechanism of action for dry eye treatment.
- DIQUAS improves symptoms of dry eye as it promotes secretion of water and mucin.
- DIQUAS was well tolerated in dry eye patients in long-term administration, and therefore is expected to have long-term improvement effect against the clinical symptoms of dry eye.
- No serious ocular or systemic adverse drug reactions have been found.

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