

News Release



Santen Announces Approval of *Diquas* for the Treatment of Dry Eye in China

November 1, 2017, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) announced today that it received an import drug license of *Diquas Ophthalmic Solution* (generic name: diquafosol sodium; hereinafter “*Diquas*”) for the treatment of dry eye in China on October 20, 2017.

In clinical trials conducted in Japan, *Diquas* was shown to improve dry eye signs and symptoms by promoting secretion of mucin and water as main components of tears, 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 is a multifactorial disease characterized by unstable tear film causing a variety of symptoms and/or visual impairment, potentially accompanied by ocular surface damage. It begins with symptoms of ocular discomfort such as burning, stinging or a foreign body sensation. However, when aggravated, the disease can become very serious when it interferes with everyday activities. Recently, studies have shown that the number of dry eye patients is increasing primarily due to increased visual activities (computer work, etc.), dry air caused by 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 China.

Santen has sold several types of ophthalmic solutions in such as the corneal and conjunctival disease area and the bacterial conjunctivitis area in China. The addition of *Diquas* to Santen’s product lineup can be a useful treatment option allowing Santen to further contribute to improvement in patient quality of life.

The impact of this approval on Santen’s financial statements is not material.

About *Diquas* in China

Generic name: Diquafosol sodium

Dosage form: Aqueous ophthalmic solution

Indication: For dry eye patients diagnosed with conjunctival epithelium injury accompanied by tear abnormalities

Dosage: 1 drop/time, 6 times daily

Product Characteristics

- *Diquas* is a P2Y₂ receptor agonist ophthalmic solution.
- *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.

About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing, and sales of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in approximately 60 countries. 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. For more details, please see Santen's website (www.santen.com).

Santen Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is 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 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.

Contact

Christopher Hohman, General Manager
Corporate Communications Group
Santen Pharmaceutical Co., Ltd.
E-mail: ir@santen.com
Tel: +81-6-4802-9360