

**Santen receives manufacturing and marketing approval for the dry-eye treatment
DIQUAS LX Ophthalmic Solution 3% in Japan**
**- Improved formulation to reduce administration frequency to three-times daily, thus easing
patients' burden -**

June 20, 2022, Santen Pharmaceutical Co., Ltd. (head office in Osaka City; hereinafter "Santen") today announced that it has obtained manufacturing and marketing approval for the dry eye treatment *DIQUAS LX Ophthalmic Solution 3%* (diquafosol sodium) in Japan.

DIQUAS LX Ophthalmic Solution 3% is a formulation that requires the administration of one drop at a time, 3 times daily, an improvement over the current *DIQUAS Ophthalmic Solution 3%* (dosage: one drop at a time, 6 times daily), which has been launched in Japan since 2010. One of the factors that causes patients to fail to adhere to administration requirement for eye drops in ophthalmic dry-eye treatment is the large number of times the eye drops must be used daily. Developing *DIQUAS Ophthalmic Solution* that requires lower administration frequency is clinically beneficial and reduces the burden of patients.

The active ingredient, diquafosol sodium, is a P2Y₂ receptor agonist that acts on conjunctival tissues to promote the secretion of tears containing water and secretory mucins. It also has the effect of promoting the expression of membrane-bound mucins on corneal epithelium. In addition to these effects, *DIQUAS LX Ophthalmic Solution 3%* boosts the lipid content in tears to quantitatively and qualitatively improve tear abnormalities, and bring the ocular surface to a normal condition to demonstrate an efficacy. *DIQUAS LX Ophthalmic Solution 3%* was verified as being superior to placebo eye drops in Phase III clinical trial covering Japanese dry-eye patients, in which the score for corneal epithelial staining from fluorescein was used as the indicator to determine the level of improvement for corneal epithelial disorders and in Phase IIIb clinical trial, the eye drop adherence rate was higher than that of the existing *DIQUAS Ophthalmic Solution 3%*. In both Phase III and Phase IIIb clinical trials, no serious ocular or systemic side effects were observed.

As a specialized company dedicated to eye health, Santen is committed to reducing the loss of social and economic opportunities for people around the world due to eye conditions. We will also enhance the level of convenience in treatments to improve medication compliance, thereby contributing to raising patients' quality of life.

About Santen

As a specialized company dedicated to eye health, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices, and its products now reach patients in over 60 countries and regions.

Toward realizing “WORLD VISION” (Happiness with Vision), the world Santen ultimately aspires to achieve, as a “Social Innovator”, we aim to reduce the social and economic opportunity loss of people around the world caused by eye diseases and defects by orchestrating and mobilizing key technologies and players around the world.

With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen’s website (<https://www.santen.com/en/>).

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