

Santen’s *Verkazia* (Cyclosporine Ophthalmic Emulsion) 0.1% Now Available for the Treatment of Vernal Keratoconjunctivitis in Children and Adults in the United States

May 2, 2022, Emeryville, Calif. – Santen Inc., the U.S. subsidiary of Santen Pharmaceutical Co., Ltd. (hereinafter, Santen), a global company focused exclusively on eye care, today announced that *Verkazia* (cyclosporine ophthalmic emulsion) 0.1% have been released in the United States for the treatment of vernal keratoconjunctivitis (VKC). *Verkazia* – which is administered as an eye drop – is the first and only FDA-approved topical immunomodulator (drug that suppresses the immune system) for the treatment of VKC in children and adults.

“We are proud to make *Verkazia* available for all those with VKC in the U.S. VKC is most common in children and adolescents that causes severe inflammation of the surface of the eye. Previously, there are no optimal treatment options for these patients in the U.S., and the disease can interfere with everyday activities,” said Shigeo Taniuchi, President and CEO of Santen. “This is also a monumental milestone for Santen, as we deliver an innovative solution that we have brought from the development stage to commercialization comprehensively within the U.S. market - the largest ophthalmology market in the world. In addition, having a treatment option for the rare disease VKC will strengthen our existing product portfolio for ocular surface disease in the United States. This is also the first step for us to address the unmet needs of VKC patients, by helping those who have been struggling with symptoms to resume their daily lives.”

Verkazia is a prescription-only, uniquely formulated cationic nanoemulsion that provides improved ocular bioavailability of cyclosporine, which has been shown to be effective in the management of VKC¹. *Verkazia* is thought to act by blocking release of pro-inflammatory cytokines – such as IL-2 – that can cause the chronic, severe, potentially debilitating allergic inflammation of the ocular surface that is seen in patients affected by VKC^{2,3}.

“The symptoms associated with VKC, such as itching and eye pain, can affect quality of life and prevent those affected from participating in normal daily activities like school or sports. And if left untreated, severe cases of VKC can even lead to vision loss,” said Dr. Sherif El-Harazi, ophthalmologist, Medical Director and Founder of Lugene Eye Institute and Global Research Management in Glendale, California. “The availability of this proven treatment will be an important new tool to help patients with VKC get back to living their lives.”

About Verkazia

Worldwide, *Verkazia* is available for the treatment of VKC in the United States, Canada, and select countries across Asia and Europe. In several countries, it has been designated as an orphan drug.

The FDA approved *Verkazia* in June 2021 based on data from two randomized, multi-center, double-masked, vehicle-controlled, clinical trials (VEKTIS Study and NOVATIVE Study). In the studies, *Verkazia* demonstrated improvements in inflammation of the cornea (keratitis score) and ocular itching. The most common adverse reactions reported in greater than 5 percent of patients were eye pain (12%) and eye pruritus (8%), which were usually transitory and occurred during instillation.

About Santen

As a specialized company dedicated to ophthalmology, 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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¹ Lallemand F, et al. Successfully Improving Ocular Drug Delivery Using the Cationic Nanoemulsion, Novasorb. *J Drug Deliv.* 2012;2012:604204. doi: 10.1155/2012/604204.

² Verkazia Prescribing Information, June 2021. <https://www.verkazia.com/pdf/Verkazia-PI.pdf>

³ Leonardi A. Management of Vernal Keratoconjunctivitis. *Ophthalmol Ther.* 2013 Dec; 2(2): 73–88. doi: 10.1007/s40123-013-0019-y.