

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% is now available in the United States for the treatment of vernal keratoconjunctivitis (VKC), a rare and recurrent allergic eye condition that causes severe inflammation of the surface of the eye. *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 United States who have lacked optimal treatment options for this condition. VKC can often disrupt everyday activities due to the debilitating symptoms including eye itching, tearing, pain, light sensitivity and even blurred vision,” 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 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 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 VKC.¹ *Verkazia* is thought to act by blocking the release of pro-inflammatory cytokines – such as IL-2 – that can cause the chronic, severe, potentially debilitating allergic inflammation of the ocular surface 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.

Verkazia is an important addition to the commercial products Santen has offered since the acquisition of Eyevance Pharmaceuticals in late 2020.

For more information, please visit www.verkazia.com.

Indication

Verkazia (cyclosporine ophthalmic emulsion) 0.1% is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

To avoid the potential for eye injury or contamination, advise patients not to touch the vial tip to the eye or other surfaces.

ADVERSE REACTIONS

The most common adverse reactions following the use of *Verkazia* were eye pain (12%) and eye pruritus (8%).

About Santen

As a global specialized company dedicated to ophthalmology, Santen brings a 130-year history of scientific knowledge and organizational capabilities to research, development, and commercialization of pharmaceuticals, surgical and medical devices, and OTC eye-care products. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan, and its products now reach patients in more than 60 countries. 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 websites www.santenusa.com and www.santen.com (Japan headquarters).

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.

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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.