

Santen Received the Approval of Verkazia® (Ciclosporin Eye Drops (III)), Providing New Solutions for Severe Vernal Keratoconjunctivitis in China

On May 10, 2022, Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) today announced that it has received approval of Verkazia® (Ciclosporin Eye Drops (III)) from the National Medical Products Administration (NMPA) in China through its Chinese legal entity for the treatment of severe vernal keratoconjunctivitis (VKC) in children and adolescents aged 4 years and above. The approval of Verkazia® will provide more effective and safe choices for ophthalmologists in terms of VKC management plans and thus benefit more VKC patients.

VKC is a rare and recurrent allergic eye condition, most common in children and adolescents, which causes severe inflammation of the ocular surface. The symptoms of VKC – intense itching, painful eyes and light sensitivity – can prevent those affected from participating in everyday activities. Without adequate treatment, severe cases may result in corneal ulcers and even vision loss.

Allergic conjunctivitis is reported to affect 40% of the population in the United States¹. In Asia, 15-20% of the Japanese population has a history of allergic conjunctivitis, with VKC accounting for 3.8% of hospital visits for allergic conjunctivitis². According to a Chinese study, VKC accounts for 11% of hospital visits for allergic conjunctivitis³. VKC is recurrent disease with a long treatment period of several months to years. Previously, there were no medications available for long-term management of VKC, especially in children, so the effective treatment options are imminent.

Verkazia® is a prescription-only, uniquely formulated cationic nanoemulsion that provides improved ocular bioavailability of ciclosporine, which has been shown to be effective in the management of VKC⁴. 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^{5,6}.

“VKC is a rare but severe disease affecting children and adolescents. Its characteristics of allergic conjunctivitis significantly affects quality of life, such as limiting academic and outdoor activities due to itching and pain that prevent the eyes from opening when symptoms occur”, said Shigeo Taniuchi, President & CEO of Santen. “In order to meet the further unmet needs of patients in China, we will continue to expand our product portfolio by developing and introducing new innovative products that meet the unmet needs of Chinese patients. We will further contribute to Chinese patients and improve eye

health in China.”

“We are proud to make Verkazia® available for children and adolescents with severe VKC in China. Previously, there were no optimal treatment options available, and the disease can interfere with everyday activities and may even lead to vision loss,” said Takayuki Yamada, Head of Santen China Business. “The approval of Verkazia® will provide a new and high-quality clinical option to severe VKC patients who have been struggling with symptoms to resume their daily lives. Verkazia®’s quick approval has demonstrated ‘China speed’, which will truly benefit patients with clinical needs. We are committed to continuing to introduce and develop innovative and quality ophthalmic solutions for the benefit of more Chinese ophthalmic patients and will collaborate with various sectors of the society to promote the development of the ophthalmic ecosystem and help achieve the goal of China’s national initiative, ‘Healthy China 2030’.”

About Verkazia®

Verkazia is available over 10 countries for the treatment of VKC in the United States, Canada, several countries in Asia and Europe. It has been designated as an orphan drug in several countries.

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 Keratology Group of the Chinese Medical Association Ophthalmology Branch. Expert consensus on the diagnosis and treatment of allergic conjunctivitis in China (2018)[J]. *Chinese Journal of Ophthalmology*,2018,54(6):409-414. (In Chinese)
- ² Takamura E, Uchio E, Ebihara N, et al. Japanese guidelines for allergic conjunctival diseases 2017[J]. *Allergol Int*, 2017, 66(2): 220-229. DOI: 10.1016/j.alit.2016.12.004.
- ³ Li Y, Zhang X, Lv L, et al. Epidemiology of allergic conjunctivitis and preliminary results of an open multicenter treatment with olopatadine eye drops[J]. *Ophthalmology*,2008,17(3):166-170. (In Chinese)
- ⁴ 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.
- ⁵ Verkazia Prescribing Information, June 2021. <https://www.verkazia.com/pdf/Verkazia-PI.pdf>
- ⁶ Leonardi A. Management of Vernal Keratoconjunctivitis. *Ophthalmol Ther*. 2013 Dec; 2(2): 73–88. doi: 10.1007/s40123-013-0019-y.

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