October 26, 2020

Santen Announces U.S. FDA Filling Acceptance of New Drug Application (NDA) for Cyclosporine Topical Ophthalmic Emulsion, 0.1% in the Treatment of Severe Vernal Keratoconjunctivitis in Patients Ages 4-18

Santen Pharmaceutical Co., Ltd. (Head Office: Osaka City, hereafter Santen), today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for cyclosporine topical ophthalmic emulsion, 0.1%, for the treatment of severe vernal keratoconjunctivitis (VKC) in patients ages 4-18. The FDA has set June 26, 2021 as the Prescription Drug User Fee Act (PDUFA) goal date.

The NDA submission for cyclosporine topical ophthalmic emulsion, 0.1% is supported by data from VEKTIS (NCT01751126), a 12-month, randomized, multi-center, double-masked, vehicle-controlled, pivotal clinical trial. In the trial, patients were randomized to either the high dose group (administered 4 times daily), low dose group (administered 2 times daily), or vehicle group for the first 4 months (Period 1). Patients randomized to the vehicle group were switched to either the high or low dose group (administered 4 times or 2 times daily) from Month 4 to Month 12 (Period 2).

About Cyclosporine Topical Ophthalmic Emulsion, 0.1%

Cyclosporine topical ophthalmic emulsion, 0.1% is an investigational treatment for severe VKC in patients ages 4-18. Worldwide, it is available for the treatment of severe VKC in ten countries across Asia, Europe, and North America (Canada).

About Vernal Keratoconjunctivitis

VKC is a rare and recurrent allergic eye condition, most common in children and adolescents, that causes severe inflammation of the surface of the eye. The symptoms of VKC – intense itching, painful eyes and light sensitivity[1,2] – can prevent those affected from participating in everyday activities.[1,2,3] Approximately one-third of VKC cases are considered severe, and without adequate treatment may result in corneal ulcers and even vision loss.[4]

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