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Ciclosporin Topical Ophthalmic Emulsion, 0.1% in the Treatment of Severe Vernal Keratoconjunctivitis in Patients Ages 4-18, has been added to China's third batch of Overseas New Drugs Urgently Needed in Clinical Settings, compiled by the NMPA

Santen Pharmaceutical Co., Ltd. (Head office in Osaka; hereinafter "Santen") has announced that the Ciclosporin Topical Ophthalmic Emulsion, 0.1% in the treatment of severe vernal keratoconjunctivitis (VKC) in patients ages 4-18, has been added to China's third batch of Overseas New Drugs Urgently Needed in Clinical Settings, compiled by the National Medical Products Administration (NMPA).

Overseas new drugs, contained in this list, have been selected by the NMPA and the National Health Commission of China and put through a special review and approval channel, which facilitates faster approval and accelerated market launch.

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]. Currently, there is no suitable treatment for long-term treatment of VKC in China, and it is a disease with high-unmet medical needs.

The MAA submission in EU for Ciclosporin Topical Ophthalmic Emulsion, 0.1%, which is approved in July, 2018, 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 Ciclosporin Topical Ophthalmic Emulsion, 0.1%

Ciclosporin 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).

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