News Release

Santen Receives Positive CHMP Opinion in Europe for Ciclosporin eye drops for the Treatment of Paediatric Patients with Severe Vernal Keratoconjunctivitis

July 26, 2017, Osaka, Japan – Santen Pharmaceutical Co., Ltd. ("Santen") today announced that the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending the marketing authorization for ciclosporin 1mg/mL eye drops, emulsion, for the treatment of severe vernal keratoconjunctivitis (VKC) in paediatric populations[1].

VKC is a severe and recurrent allergic eye condition, which predominantly affects children (mainly boys) and young adults. The condition is characterised by severe inflammation of the eye surface, including the conjunctiva and cornea. VKC results in intense itching, photophobia, painful eyes and even potential permanent loss of vision.[2] Currently, there is no approved therapy in Europe that targets the underlying immune process which initiates and perpetuates the inflammation in VKC. If approved by the European Commission (EC), ciclosporin (1mg/mL, eye drops) will be the first medicine for the management of severe VKC.

Ciclosporin 1mg/mL eye drops were assessed for their effectiveness and tolerability in a multi-centre, randomised, double-masked, three parallel-arms, vehicle-controlled Phase III clinical trial, referred to as Vektis. Vektis included 169 children and adolescents between the ages of 4-18 years who were diagnosed with severe VKC. The Vektis clinical trial met its primary and key secondary endpoints.[3]

"The CHMP positive opinion recommending the marketing authorization for this product under accelerated conditions is a major milestone in this centralized procedure. This project underlines our mission of improving the quality of life for all patients, including those suffering from severe and rare paediatric, conditions," said Naveed Shams, M.D., Ph.D., Chief Scientific Officer and Head of Global R&D at Santen.

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About Ciclosporin 1mg/mL eye drops

Ciclosporin 1mg/mL eye drops has been developed as a sterile, positively charged (i.e. cationic), oil-in-water emulsion. This cationic emulsion, developed using Santen's Novasorb® proprietary technology, improves the delivery of ciclosporin into the eye.[4]

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About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing, and sales of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in approximately 60 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see Santen's website (www.santen.com).

Santen Forward-Looking Statements

Information provided in this press release contains so-called “Forward-looking Statements.” The realizations of these forecasts are 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 condition are subject to the effects of change 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.

References

1. European Medicines Agency - News and Events - New medicine for rare form of eye allergy in children and teenagers
2. Leonardi A. Management of vernal keratoconjunctivitis. *Ophthalmol Ther* 2013;2:73–88
3. Andrea Leonardi, et al. Topical Ciclosporin A 1 mg/mL Cationic Emulsion in the Treatment of Active Severe Vernal Keratoconjunctivitis (VKC) in Pediatric Patients: Results of the Phase III VEKTIS Study. ARVO 2017.
4. Lallemand F, et al. Successfully improving ocular drug delivery using the cationic nanoemulsion, Novasorb. *J Drug Deliv* 2012;2012:604204