

Santen Receives Marketing Authorisation from the European Commission for DE-076C (*Verkazia*) as an Orphan Medicinal Product

July 10, 2018 - Santen Pharmaceutical Co., Ltd. (Head office: Osaka, Japan; Chairman and CEO: Akira Kurokawa) announced that the European Commission has granted marketing approval for DE-076C (*Verkazia*[®] eye drop emulsion containing 0.1% (1mg/ml) ciclosporin, hereafter *Verkazia*) as an orphan medicinal product. *Verkazia* is indicated for treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.

Santen has been highly committed to developing this important new orphan medicinal product for children suffering this distressing and chronically debilitating condition that has rare disease status in Europe.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 No other comparable treatment has been licensed by the EMA. Thus, *Verkazia* is considered to have a significant benefit to those affected by this condition.

A pivotal phase III trial demonstrated that *Verkazia* improves ocular surface damage and reduces symptoms of severe VKC in children and adolescent patients.²

Luis Iglesias, President and Head of Santen EMEA comments: “Santen’s focus on rare diseases is allowing us to meet real unmet needs across disease areas, in this case VKC. Our innovative medicines pipeline which includes therapies for early and late stage glaucoma as well as intraocular inflammation is further evidence of our desire to continuously meet the expectations of our patients and ophthalmologists in Europe and beyond.”

The impact of this approval on Santen’s published forecasts for the fiscal year ending March 31, 2019 is not material.

References

1. Public summary of opinion on orphan designation, Ciclosporin for the vernal keratoconjunctivitis, European Medicines Agency, April 2015:
http://www.ema.europa.eu/docs/en_GB/document_library/Orphan_designation/2009/10/WC500006038.pdf

2. Leonardi A, et al. Topical Ciclosporin A 1mg/mL Cationic Emulsion in the Treatment of Active Severe Vernal Keratoconjunctivitis (VKC) in Pediatric Patients: Results of the Phase III VEKTIS Study. 2017 Annual Meeting of the Association for Research in Vision and Ophthalmology; May 7–11, 2017; Baltimore, Maryland

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. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a nearly 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 (www.santen.com).

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