Press Release

Santen Receives U.S. FDA Approval for Verkazia (Cyclosporine Ophthalmic Emulsion, 0.1%) for the Treatment of Vernal Keratoconjunctivitis in Children and Adults

June 24, 2021, Osaka, Japan– Santen Pharmaceutical Co., Ltd. (hereinafter, Santen), today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Verkazia (Cyclosporine ophthalmic emulsion, 0.1%) for the treatment of vernal keratoconjunctivitis (VKC) in children and adults. Santen had received initial FDA filing acceptance on October 26, 2020. With this approval, Santen is now working to make a new treatment option available for patients in the United States.

VKC is a rare and recurrent allergic eye condition, mainly occurring 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 – can prevent those affected from participating in everyday activities.[1,2,3] Without adequate treatment, severe cases may result in corneal ulcers and even vision loss.[4]

"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. "We will leverage our U.S. business foundation of Eyevance which was acquired by Santen in September 2020. We are thrilled to be collaborating with healthcare professionals to deliver treatment to this underserved population as soon as possible, and we hope to bring smiles back to children and patients in the United States."

"We're extremely happy to have received FDA approval as our first internal prescription product approval in the U.S. market." stated Tatsuya Kaihara, CEO of Santen Inc. and Head of Santen North America. "This is an important milestone in Santen's aim to bring innovative solutions that protect vision for those affected by ophthalmic conditions. With this approval doctors and patients in the United States now have an effective and new treatment for this rare condition that may allow those affected to continue taking part in everyday activities."

"Following Europe, Asia and Canada, we have now also received approval in the United States, demonstrating Santen's global development commitment. We would like to continuously deliver "Happiness with Vision" to children around the world whose daily activities are restricted by VKC." said Peter Sallstig, Corporate Officer and Head of Product Development Division at Santen.

About Verkazia

Verkazia is a prescription-only, uniquely-formulated oil-in-water cationic emulsion that provides improved ocular bioavailability of cyclosporine, which has been shown to be effective in the management of VKC. It works by inhibiting T-cell activation and reducing the level of immune cells and mediators that cause the chronic, severe, potentially debilitating allergic inflammation of the ocular surface that is seen in those affected by VKC. Worldwide, Verkazia is available for the treatment of VKC in more than 10 countries across Asia, Europe, and Canada.

About Clinical Data

The FDA approval for Verkazia was based on data from the pivotal VEKTIS study and the phase 2/3 NOVATIVE study which assessed the efficacy and tolerability of Verkazia for treating active VKC in children and adolescents. In the studies, Verkazia demonstrated improvements in inflammation of the cornea (keratitis score) and ocular itching.

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.

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 (www.santen.com).

Contact

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