Press Release

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

June 24, 2021, Emeryville, California – Santen Inc., the U.S. subsidiary of Santen Pharmaceutical Co., Ltd. (hereinafter, Santen), a global company focused exclusively on eye care, today announced that the U.S. Food and Drug Administration (FDA) has approved Verkazia™ (cyclosporine ophthalmic emulsion) 0.1% eye drops for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

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 – 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]

“This is an important milestone in Santen’s aim to bring innovative solutions that protect vision for those affected by rare ophthalmic conditions, and is the first prescription product approval for Santen in the U.S. market,” said Tatsuya Kaihara, CEO of Santen Inc. and Head of Santen North America. “If left untreated, VKC is associated with symptoms such as eye pain and vision loss that can have detrimental impacts on those it affects, including on school attendance and academic performance. With this approval, doctors and patients in the U.S. now have an effective and sustainable treatment for this rare condition that may allow those affected to continue taking part in everyday activities.”

How Verkazia Works

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 select countries across Asia, Europe, and North America.

Verkazia Clinical Data

The safety and efficacy of Verkazia for the treatment of VKC was evaluated in two randomized, multi-center, double-masked, vehicle-controlled, clinical trials (VEKTIS Study and NOVATIVE Study). In the VEKTIS study, patients with severe VKC were randomized to four times daily of Verkazia 1 mg/mL or two times daily (BID) of Verkazia 1 mg/mL and vehicle group for the first 4 months (Period 1). Similarly, in the

NOVATIVE study, patients with moderate to severe VKC were randomized to QID of Verkazia 1 mg/mL or QID of cyclosporine ophthalmic emulsion 0.5 mg/mL and vehicle group for the first 1 month (Period 1). In both studies, patients randomized to the vehicle group were switched to Verkazia (QID or BID) from Month 4 to Month 12 in VEKTIS Study and to cyclosporine ophthalmic emulsion 0.5 mg/mL QID or 1 mg/mL from Month 1 to Month 4 in NOVATIVE Study (Period 2).

In the studies, Verkazia demonstrated improvements in inflammation of the cornea (keratitis score) and ocular itching. The most common adverse reactions reported in greater than 5 percent of patients were eye pain (12%) and eye pruritus (8%), which were usually transitory and occurred during instillation.

Indication

Verkazia (cyclosporine ophthalmic emulsion) 0.1% is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

To avoid the potential for eye injury or contamination, advise patients not to touch the vial tip to the eye or other surfaces.

ADVERSE REACTIONS

The most common adverse reactions following the use of Verkazia were eye pain (12%) and eye pruritus (8%).

About Santen

As a global specialized company dedicated to ophthalmology, Santen brings a 130-year history of scientific knowledge and organizational capabilities to research, development, and commercialization of pharmaceuticals, surgical and medical devices, and OTC eye-care products. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in more than 60 countries. 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 websites www.santenusa.com and www.santen.com (Japan headquarters).

Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is 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 conditions are subject to the effects of changes 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.

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