Press Release

Santen Announces U.S. FDA Filing Acceptance of New Drug Application (NDA) for Cyclosporine Topical Ophthalmic Emulsion, 0.1% for the Treatment of Severe Vernal Keratoconjunctivitis in Patients Ages 4-18

October 26, 2020, Emeryville, CA – Santen Inc., the U.S. subsidiary of Santen Pharmaceutical Co., Ltd. (hereinafter, Santen), a global company focused exclusively on ophthalmology, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for cyclosporine topical ophthalmic emulsion, 0.1% for the treatment of severe vernal keratoconjunctivitis (VKC) in patients ages 4-18. The FDA has set June 26, 2021 as the Prescription Drug User Fee Act (PDUFA) goal date.

"This is an important milestone for patients with severe vernal keratoconjunctivitis in the U.S. – especially children and adolescents – and the doctors who treat them," said Peter Sallstig, Senior Vice President and Global Head Product Development Division of Santen. "We look forward to working with the FDA during the review process and are optimistic this treatment could provide much needed symptom relief for those affected so they may better engage in their daily activities."

The NDA submission for cyclosporine topical ophthalmic emulsion, 0.1% 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 Cyclosporine Topical Ophthalmic Emulsion, 0.1%

Cyclosporine 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).

About Vernal Keratoconjunctivitis (VKC)

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] Approximately one-third of VKC cases are considered severe, and without adequate treatment may result in corneal ulcers and even vision loss.[4]

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 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 websites www.santenusa.com and www.santen.com (Japan headquarters).

Forward-looking Statements

Statements included in this press release are or may be considered forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Santen that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties from various sources. 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. Santen undertakes no obligation to update forward-looking statements as a result of subsequent events or developments, except as required by law.

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