News Release

Santen Receives Complete Response Letter from U.S. FDA for Intravitreal Sirolimus (DE-109)

December 21, 2017 – Santen Pharmaceutical Co., Ltd. (Osaka, Japan) and Santen Inc. (Emeryville, CA, USA) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter for the New Drug Application (NDA) for intravitreal (IVT) sirolimus (DE-109). IVT sirolimus is an investigational therapy developed as a potential treatment for adults with noninfectious uveitis of the posterior segment, a leading cause of preventable blindness in working-age adults.[1]

The complete response letter indicates that the FDA is unable to approve the application in its present form and requests additional substantiating evidence to demonstrate efficacy of IVT sirolimus in the treatment of noninfectious uveitis of the posterior segment.

“We are evaluating the FDA’s response and will work closely with the agency to determine the best path forward. We strongly believe in the benefits of IVT sirolimus for noninfectious uveitis of the posterior segment patients, and will continue to work towards our goal of bringing a local, non-steroidal therapy to patients suffering from this sight-threatening disease," said Naveed Shams, MD, PhD, Chief Scientific Officer and Head of Global Research and Development of Santen. "Santen remains focused on our mission to develop and provide innovative therapies to patients suffering from ophthalmic diseases in the United States and around the world."

The CRL is not expected to have a material impact on FY2017 earnings forecasts.

About Intravitreal (IVT) Sirolimus (DE-109)

IVT sirolimus is being evaluated as a potential treatment for adults with noninfectious uveitis of the posterior segment (intermediate, posterior and panuveitis). IVT sirolimus is a locally-administered, non-steroidal immunoregulator that has been investigated for the resolution of intraocular inflammation associated with noninfectious uveitis of the posterior segment. The New Drug Application for IVT sirolimus was supported by the results from the SAKURA (Sirolimus study Assessing double-masKed Uveitis tReAtment) Program, the largest Phase III global program for noninfectious uveitis of the posterior segment to date. The SAKURA Program included two multi-national, randomized, double-masked, active-controlled studies in adult patients with active non-infectious intermediate, posterior or panuveitis.

About Noninfectious Uveitis of the Posterior Segment

Uveitis is a group of eye disorders affecting the uvea, which are characterized by intraocular inflammation that is often chronic, can flare up at any time, and can lead to visual impairment and vision loss.[1,2] Despite being a rare disease, uveitis has been

estimated to be responsible for approximately five to 20 percent of all cases of legal blindness and visual handicap in the United States and Europe.[3] In the developing world, uveitis is responsible for 25 percent of all cases of blindness.[3]

Noninfectious uveitis of the posterior segment constitutes 15 to 22 percent of all cases of uveitis[4] and impacts the posterior segment of the eye, including the vitreous, retina, choroid and/or optic nerve.[1] Noninfectious uveitis of the posterior segment occurs most often in adults between ages 20 and 50, and affects fewer than 200,000 people in the United States.[5]

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.SantenUSA.com).

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.

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