News Release

Santen Announces U.S. FDA Filing Acceptance of New Drug Application (NDA) for Intravitreal Sirolimus (DE-109) in the Treatment of Non-Infectious Uveitis of the Posterior Segment

April 25, 2017, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, "Santen"), a specialized ophthalmology company headquartered in Osaka, Japan, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for intravitreal (IVT) sirolimus (440 µg), development code DE-109, for the treatment of non-infectious uveitis of the posterior segment (NIU-PS). The FDA has set an action date of December 24, 2017 to complete its review of the IVT sirolimus NDA, per the Prescription Drug User Fee Act (PDUFA). IVT sirolimus was granted orphan drug designation by the FDA and the European Commission (EC) in 2011.

IVT sirolimus, an mTOR inhibitor, is an investigational first-in-class targeted, immunoregulator being developed by Santen for the treatment of patients with NIU-PS. NIU-PS is a progressive and chronic inflammatory disease of the eye that can lead to vision impairment and blindness. The NDA for IVT sirolimus is supported by data from the SAKURA Program, the largest Phase III global clinical program to date evaluating patients with NIU-PS.

"The FDA acceptance of the NDA for IVT sirolimus is an important milestone, and brings us closer to potentially offering a locally-administered treatment option for patients with NIU-PS," said Naveed Shams, M.D. Ph.D, Chief Scientific Officer and Head of Global R&D at Santen.

About IVT Sirolimus

IVT sirolimus (440 µg), an mTOR inhibitor, is a first-in-class targeted, immunoregulator being developed for the treatment of NIU-PS – a progressive and chronic inflammatory disease of the eye. IVT sirolimus inhibits the protein kinase, mTOR which plays a key role in inflammation. The result is immunoregulation by: interrupting the inflammatory cascade through the inhibition of T-cell activation, differentiation and proliferation; and, promoting immune tolerance, increasing regulatory T lymphocytes (Tregs).

About Uveitis

Uveitis is a leading cause of preventable blindness in working-age adults and is estimated to account for 10 to 15 percent of cases of total blindness in the developed world.[1] It is characterized by intraocular inflammation that is often chronic, can flare up at any time and can lead to visual impairment and vision loss. NIU-PS includes intermediate, posterior and panuveitis.

About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing, and sales of pharmaceuticals and devices. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in over 50 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.santen.com).

Santen 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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[1] Durrani OM, Tehrani NN, Marr JE, Moradi P, Stavrou P, Murray PI. Degree, duration, and causes of visual loss in uveitis. *Br J of Ophthalmol*. 2004;88(9):1159-1162.

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