

Santen and Glaukos Enter into a New Collaboration in the Development and Commercialization of STN2000100 (DE-128) in the Americas, Australia, and New Zealand

May 19, 2021, Osaka, Japan— Santen Pharmaceutical Co., Ltd. (“Santen”) announced that it has entered into an expanded collaboration in the development and commercialization with Glaukos Corporation (San Clemente, CA, U.S.A; “Glaukos”) for the product development, commercialization, and sales of the Santen-owned STN2000100 surgical device (“DE-128”) in the Americas (North, Central, and South America), Australia, and New Zealand. The two companies signed agreements in April 2019 and September 2020 whereby Glaukos became the exclusive distributor of DE-128 in the U.S. market and Australia and New Zealand markets, respectively, but this will be expanded in the development and commercialization agreement to develop and commercialize DE-128 in the aforementioned countries.

By offering the rights to product development, commercialization, and sales in said regions, Santen transfers to Glaukos all DE-128-related regulatory affairs, clinical development activities tailored to obtaining approval for the surgical device, and all commercialization endeavors including marketing. Santen continues to manufacture DE-128 and supply it to Glaukos. Santen also continues to develop and commercialize DE-128 in regions other than the Americas, Australia and New Zealand.

To expand its glaucoma portfolio, in August 2016 Santen acquired U.S. startup and DE-128 developer InnFocus, Inc., and accordingly launched sales in Europe. Santen subsequently submitted a Premarket Approval (PMA) to the U.S. Food and Drug Administration (FDA), which was accepted in July 2020. After receiving the FDA’s feedback in late February 2021 about the review, Santen went into discussions with Glaukos over the development and commercialization of DE-128. The two companies discussed how to obtain approval as early as feasible, and in turn decided to collaborate in the development and commercialization endeavors in the Americas, Australia, and New Zealand by leveraging Glaukos’ expertise in glaucoma surgery.

Santen aspires to steadfastly monetize its U.S. operations through appropriate commercialization strategies and resource allocation by harnessing the business foundation of U.S.-based firm Eyevance, as well as through late-stage clinical product development. By adopting Glaukos’s development and commercialization model, Santen is also expecting to reduce upfront investment and in turn reliably gain profit from DE-128. By focusing its resources to pharma and creating a positive cycle that further increases R&D and business development capabilities within North America, Santen will endeavor to lay a foundation for pharmaceuticals and establish its corporate presence within the U.S., a country that accounts for the world’s largest share in the ophthalmology market.

About STN2000100 (DE-128)

In the United States, STN2000100 (DE-128) is an investigational, ab-externo, minimally-invasive surgical glaucoma implant designed to help drain eye fluid and reduce intraocular pressure (IOP) in primary open-angle glaucoma patients whose IOP is not controlled when using maximum tolerated glaucoma medications. IOP reduction is the most effective means of preventing the progression of glaucoma and vision loss. Made of a proprietary, biocompatible material called SIBS [poly (styrene-block-isobutylene-block-styrene)],

STN2000100 (DE-128) is a flexible, 8.5-mm-long tube with planar fins to help fixate the device in tissue and prevent leakage and migration.

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).

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. The company pioneered Micro-Invasive Glaucoma Surgery, or MIGS, to revolutionize the traditional glaucoma treatment and management paradigm. Glaukos launched the *iStent*[®], its first MIGS device, in the United States in 2012, its next-generation *iStent inject*[®] device in the United States in 2018, and most recently, the *iStent inject W* device in 2020. In corneal health, Glaukos' proprietary suite of single-use, bio-activated pharmaceuticals are designed to strengthen, stabilize and reshape the cornea through a process called corneal collagen cross-linking to treat corneal ectatic disorders and correct refractive conditions. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

Santen 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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