



Santen and Glaukos Enter into Collaboration and Distribution Agreement for Exclusive Distribution of the MicroShunt (DE-128) in the United States

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OSAKA, Japan & SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Santen Pharmaceutical Co., Ltd. ("Santen" TSE: 4536) and Glaukos Corporation ("Glaukos" NYSE: GKOS), announced today that Santen's U.S. subsidiary, Santen Inc., has entered into a multi-year agreement whereby Glaukos will become the exclusive distributor of the MicroShunt (development code: DE-128) solely in the U.S. market.

The MicroShunt is a novel, minimally-invasive, ab-externo surgical device being developed for primary open-angle glaucoma (POAG). Glaucoma is a leading cause of irreversible blindness, affecting several million people in the United States. POAG is the most common form of the disease in people aged 40 years and older.

The MicroShunt is being studied in a U.S. Food and Drug Administration (FDA) pivotal trial (NCT01881425) for intraocular pressure (IOP) reduction in patients with POAG where intraocular pressure is uncontrolled with maximum tolerated medical therapy or where the progression of the disease warrants surgery. Following anticipated completion of the premarket approval (PMA) submission in 2019, Santen intends to seek U.S. FDA PMA and, if approved, launch of the product in the United States is targeted within calendar year 2020.

"Santen is very excited to partner with Glaukos whose proven surgical glaucoma expertise and established distribution and sales infrastructure in the United States are unparalleled," said Shigeo Taniuchi, President and Chief Operating Officer at Santen. "We strongly believe that this partnership will bring MicroShunt, if approved, to physicians and patients in the United States in the most timely, efficient and effective way possible."

"We expect Santen's MicroShunt to complement our expanding portfolio of ab-interno MIGS products by providing glaucoma patients with this ab-externo alternative to conventional filtration surgeries," said Thomas Burns, Glaukos' President and Chief Executive Officer. "We are enthusiastic about the opportunity to leverage our best-in-class sales organization and established commercial presence to partner with Santen and bring this novel technology to the United States if approved by the FDA."

The agreement stipulates that upon potential U.S. regulatory approval, Glaukos will be the exclusive distributor of the MicroShunt in the United States, responsible for sales and distribution of the product. Santen will be responsible for marketing activities as well as maintaining responsibility for all aspects of the product's manufacture, quality and safety controls, regulatory activities, life-cycle

management and post-approval marketing requirements. Financial terms of the agreement were not disclosed.

About MicroShunt (DE-128)

In the United States, the MicroShunt (DE-128) is an investigational ab-externo, minimally-invasive surgical implant being studied for the treatment of primary open angle glaucoma (POAG) in patients where intraocular pressure (IOP) is uncontrolled under maximum tolerated medical therapy or where the progression of disease warrants surgery. Made of a proprietary, biocompatible material called SIBS [poly(styrene-block-isobutylene-block-styrene)], the MicroShunt is the first glaucoma device to be compared head-to-head with trabeculectomy, in a prospective, randomized, masked, multicenter study. MicroShunt has been marketed under a CE mark in Europe as InnFocus MicroShunt and is now in the process of rebranding under the new global commercial name of PRESERFLO[®] MicroShunt.

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 nearly 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 the development and commercialization of novel surgical devices and sustained pharmaceutical therapies designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. 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 July 2012 and launched its next-generation *iStent inject*[®] device in the United States in September 2018. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale injectable therapies designed to address the complete range of glaucoma disease states and progression. The company believes the *iStent inject*, measuring 0.23 mm wide and 0.36 mm long, is the smallest medical device ever approved by the FDA.

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.

Glaukos Forward-Looking Statements

All statements other than statements of historical facts included in this press release that address

activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for forward-looking statements contained herein, we caution you that they are based on current expectations about future events affecting us and are subject to risks, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control, that may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this press release. These potential risks and uncertainties include, without limitation, whether the MicroShunt will receive FDA approval, the extent to which the MicroShunt device will or will not demonstrate continued significant sustained IOP reductions; the ability of Glaukos to successfully leverage its sales organization and establish a commercial presence for the MicroShunt, resulting in any incremental revenue for Glaukos; and the extent to which Glaukos and Santen can work cooperatively under the terms of the Collaboration and Distribution Agreement. These risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2018. Our filings with the Securities and Exchange Commission are available in the Investor Section of our website at www.glaukos.com or at www.sec.gov. In addition, information about the risks and benefits of our products is available on our website at www.glaukos.com. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof. We do not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

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