

Santen, Glaukos collaborate for exclusive distribution of the MicroShunt in the U.S.

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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 and Glaukos have announced 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 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.