

## **Santen Announces U.S. FDA Acceptance of Premarket Approval (PMA) Application for DE-128 (MicroShunt) for Review**

July 7, 2020, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) today announced that the United States Food and Drug Administration (FDA) has accepted the Premarket Approval (PMA) application for DE-128 (MicroShunt) for review. DE-128 is an investigational surgical glaucoma implant designed to reduce intraocular pressure (IOP) in patients with primary open-angle glaucoma (POAG) whose IOP is not controlled when using maximum tolerated glaucoma medications.

The substantive review, which traditionally spans 180 days from the FDA's receipt of the PMA final module, is an in-depth review following which the FDA will make a decision as to whether the PMA is approved.

As of this year, it is expected that 3.7 million people in America will be living with POAG, a leading cause of blindness.<sup>1,2</sup> The prevalence of POAG is expected to rise to 4.1 million in 2025.<sup>1</sup>

### **About DE-128 (MicroShunt)**

In the United States, DE-128 is an investigational, ab-externo, minimally-invasive surgical glaucoma implant designed to help drain eye fluid and reduce IOP in patients with POAG 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)], DE-128 is a flexible, 8.5-mm-long tube with planar fins to help fixate the device in the 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. 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 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](http://www.santen.com)).

### **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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<sup>1</sup> Kapetanakis VV, Chan MPY, Foster PJ, Cook DG, Owen CG, Rudnicka AR. Global variations and time trends in the prevalence of primary open angle glaucoma (POAG): a systematic review and meta-analysis. Br J Ophthalmol 2016;100:86–93.

<sup>2</sup> Glaucoma Research Foundation. Glaucoma Facts and Stats. Available at <https://www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php>. Accessed April 8, 2020.