Glaukos to Begin Randomized U.S. IDE Pivotal Clinical Trial for the iStent SA™ System

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Trial Protocol Calls for Enrollment of Pseudophakic Glaucoma Subjects and One Year of Follow-up to Assess the Device's Safety and Efficacy for Reduction of Elevated Intraocular Pressure

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, today announced that the U.S. Food and Drug Administration (FDA) is allowing the company to move forward with a U.S. Investigational Device Exemption (IDE) pivotal study of its *iStent SA™ Trabecular Micro-Bypass System.*

The *iStent SA* is intended for use as a standalone procedure for the reduction of intraocular pressure (IOP) in pseudophakic, mild-to-moderate primary open-angle, pigmentary or pseudoexfoliative glaucoma patients. Pseudophakic refers to patients who have previously undergone cataract surgery and no longer have a natural crystalline lens. The *iStent SA* consists of two micro-scale titanium stents that are preloaded in an auto-injection system, which allows a surgeon to inject stents into multiple trabecular meshwork locations through a single corneal entry point. Once placed, the stents are designed to restore physiological outflow of aqueous humor through the trabecular meshwork and into Schlemm's canal, the eye's primary drainage system.

The multi-center, pivotal phase randomized trial will enroll approximately 400 subjects and evaluate *iStent SA* compared to selective laser trabeculoplasty (SLT), a procedure where short laser pulses are used to target specific trabecular meshwork cells in order to increase aqueous humor outflow. Approximately 80 additional subjects from the initial trial phase will also be included in the pivotal trial. The primary efficacy endpoint is non-inferiority to SLT at one year postoperative.

"We are delighted that our successful collaboration with the FDA allows Glaukos to begin the pivotal phase of this first-ever standalone Micro-Invasive Glaucoma Surgery, or MIGS, trial," said Thomas Burns, president and chief executive officer. "We pioneered MIGS to overcome the challenges of conventional glaucoma therapies. Our commencement of the *iStent SA* trial brings us a step closer to making an approved MIGS option available to address an unmet clinical need and to treat a wider cohort of glaucoma patients."

The *iStent SA* relies on the same fluidic method of action as the company's first-generation *iStent®* *Trabecular Micro-Bypass Stent*, which has been shown to lower IOP in adult cataract patients with mild-to-moderate open-angle glaucoma. Each *iStent SA* stent is approximately 0.4 mm x 0.4 mm, or about one-third the size of *iStent*, which the company believes is the smallest medical device ever approved

by the FDA.

Glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. There is no cure for the disease and reducing IOP is the only proven treatment. Based on analysis of population-based surveys, medical claims data and other statistics, the company estimates that there are approximately 5.4 million people in the U.S. with primary open-angle glaucoma, the most common form of the disease. Glaukos estimates that approximately one-third of this U.S. primary open-angle glaucoma population is pseudophakic.

About *iStent Trabecular Micro-Bypass Stent (U.S.)*

Indication for Use: The *iStent Trabecular Micro-Bypass Stent* is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Contraindications: The *iStent* is contraindicated in eyes with primary or secondary angle closure glaucoma, including neovascular glaucoma, as well as in patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

Warnings: Gonioscopy should be performed prior to surgery to exclude PAS, rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. The *iStent* is MR-Conditional, meaning that the device is safe for use in a specified MR environment under specified conditions, please see label for details.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the *iStent* has not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, chronic inflammation, or an abnormal anterior segment, in pseudophakic patients with glaucoma, in patients with pseudoexfoliative glaucoma, pigmentary, and uveitic glaucoma, in patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg after “washout” of medications, or in patients with prior glaucoma surgery of any type including argon laser trabeculoplasty, for implantation of more than a single stent, after complications during cataract surgery, and when implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract.

Adverse Events: The most common postoperative adverse events reported in the randomized pivotal trial included early postoperative corneal edema (8%), BCVA loss of ≥ 1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%), early postoperative anterior chamber cells (3%), and early postoperative corneal abrasion (3%). Please refer to Directions for Use for additional adverse event information.

Caution: Federal law restricts this device to sale by, or on the order of, a physician. Please reference the Directions for Use labeling for a complete list of contraindications, warnings, precautions, and adverse events.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures 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 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*, measuring 1.0 mm long and 0.33 mm wide, is the smallest medical device ever approved by the FDA.

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, our ability to successfully complete the necessary clinical trial and secure U.S. regulatory approval for the *iStent SA* and our other pipeline products and the extent to which the *iStent SA* and our other pipeline product obtain market acceptance. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the Securities and Exchange Commission. 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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