Prospective, Randomized Trial Highlights 5-Year Performance of 2 Standalone Glaukos iStents® vs. Topical Prostaglandin in Newly Diagnosed Glaucoma Patients

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iStent Cohort Achieved Significantly Higher Treatment Success And Significantly Fewer iStent Subjects Required Add-on Medications at 5 Years Postoperative, Compared to Topical Prostaglandin Subjects

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE:GKOS), 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, announced today that results of an international glaucoma study published in *Ophthalmology Glaucoma* showed standalone implantation of two *iStent*® *Trabecular Micro-Bypass Stents* in newly diagnosed primary open-angle glaucoma (POAG)eyes achieved a 35.3% reduction in mean intraocular pressure (IOP) to 16.5 mmHg after five years of follow-up.

The purpose of this prospective, randomized, controlled, multi-surgeon clinical trial was to evaluate the five-year safety and efficacy of two *iStents* vs. topical prostaglandin as an initial intervention in POAG subjects who had not had prior glaucoma treatment of any kind. A total of 101 subjects were randomized in a 1:1 ratio to receive either two *iStents* in a standalone procedure or once-daily topical travoprost, a commonly prescribed prostaglandin. At five years, results showed:

- Mean diurnal IOP was 16.5 mmHg (35.3% reduction; $p < 0.0001$) for the stent group vs. 16.3 mmHg (35.1% reduction) for the travoprost group, excluding eyes in both cohorts that underwent cataract surgery during follow-up.
- Treatment success – defined as mean diurnal IOP of 6 mmHg to 18 mmHg without add-on medication or secondary glaucoma surgery – was achieved in 77% of stent eyes vs. 53% of travoprost eyes ($p = 0.04$).
- Seventeen percent of stent eyes vs. 44% of travoprost eyes required add-on medication.
- The need for add-on medication arose at a slower rate in the stent group than in the travoprost group, especially after two years of follow-up. Study authors observed that from two to five years of follow-up, add-on medications were initiated in roughly double the number of travoprost eyes vs. stent eyes.
- The safety profile was excellent in both groups throughout follow-up.

“These results illustrate the enduring efficacy and safety of using multiple trabecular bypass stents in a standalone procedure as initial intervention to manage IOP in newly diagnosed, treatment-naïve

glaucoma patients," said Robert D. Fechtner, MD, an ophthalmic surgeon based in Syracuse, NY and lead author of the *Ophthalmology Glaucoma* article. "Topical ocular hypotensive medications are typical first-line glaucoma therapy but these drugs can be ineffective due to high rates of patient non-adherence, ocular surface damage, cost and other factors. This study shows that not only are Glaukos' *iStents* as effective as once-daily topical travoprost in controlling IOP, but they also succeed at maintaining IOP reductions over the long-term with fewer additional medications."

Three-year outcomes of this study were published in 2016 in *Ophthalmology and Therapy*. The most recent article detailing five-year outcomes may be accessed online here.

"This latest publication represents the first-ever five-year, protocol-driven, randomized evaluation of standalone *iStent* implantation in newly diagnosed glaucoma patients," said Thomas Burns, Glaukos president and chief executive officer. "Moreover, it adds meaningful outcomes data to the growing body of peer-reviewed evidence that implantation of a single or multiple *iStents* can reliably achieve sustained IOP reductions in an elegant, tissue-sparing procedure with a highly favorable safety profile."

Glaukos, the study sponsor, is the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS. The U.S. Food & Drug Administration (FDA) approved the company's first MIGS device, the *iStent,* in 2012 and approved its second-generation *iStent inject®Trabecular Micro-Bypass System* in 2018. Inserted through a small corneal incision made during cataract surgery, the *iStent* is designed to reduce IOP by restoring the natural physiological outflow of aqueous humor. The *iStent inject* relies on the same fluidic method of action but is designed to deploy two stents into separate trabecular meshwork locations through a single corneal entry point for enhanced IOP reduction and procedural ease. The *iStent inject* is also approved for use in conjunction with cataract surgery or as a standalone procedure in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore, South Africa and other international markets.

Glaucoma is characterized by progressive, irreversible vision loss caused by optic nerve damage. There is no cure for the disease. However, by reducing the eye pressure, the only proven effective treatment, vision may be stabilized. 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 POAG, the most common form of the disease.

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

Indication for Use: The *iStent inject Trabecular Micro-Bypass System* Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate primary open-angle glaucoma.

Contraindications: The *iStent inject* is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber angle, retrobulbar tumor, thyroid eye disease, or 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 congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

MRI Information: The *iStent inject* is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the *iStent inject* have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents.

Adverse Events: Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent inject vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%).

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

For more information, visit www.glaukos.com.

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 intraocular pressure (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 post-operative adverse events reported in the randomized pivotal trial included early post-operative corneal edema (8%), BCVA loss of ≥ 1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%) early post-operative anterior chamber cells (3%), and early post-operative 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 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.

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, the continued efficacy and safety profile of our products as might be suggested in the published research referenced above. 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 fiscal 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.comor 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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