Glaukos iStent inject® Implantation with Concomitant Cataract Surgery Provides Sustained Reduction in IOP and Medication Burden, According to New Study

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Three-Year Outcomes Reveal 37% Mean IOP Decline to 14.3 mmHg, 68% Decline in Mean Number of Topical Ocular Hypotensive Medications and Favorable Safety Profile

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 a single-site international study of glaucoma subjects recently published in Ophthalmology and Therapy showed that the *iStent inject® Trabecular Micro-Bypass System*,combined with cataract surgery, achieved a 37% reduction in mean intraocular pressure (IOP) to 14.3 mmHg after three years of follow-up.

The prospective, non-randomized, consecutive case series was conducted by Fritz H. Hengerer, MD at the University of Heidelberg in Heidelberg, Germany and included 81 eyes of 55 glaucoma subjects undergoing cataract surgery. The cohort's preoperative mean medicated IOP was 22.6 mmHg and the preoperative mean number of topical ocular hypotensive medications was 2.5. Approximately 32% of eyes had undergone prior glaucoma surgery and 56% of eyes were on at least three medications prior to *iStent inject* implantation.

Additional study findings for subjects followed through three years (n=41 eyes) included:

- Mean medication burden decreased 68% to 0.8.
- 93% of eyes experienced reduced medications; 54% of eyes were medication free vs. 1% preoperatively.
- All eyes achieved IOP at or below 18 mmHg and 71% achieved IOP at or below 15 mmHg.
- IOP was reduced by 20% or greater in 78% of eyes.
- The safety profile was favorable with no intraoperative complications or significant side effects reported.

"These study results are particularly noteworthy because they were achieved across a clinically diverse patient population that reflects a real-world practice," said Dr. Hengerer, who performed all of the procedures and authored the study. "The results show that *iStent inject* in combination with cataract surgery is a procedure capable of delivering substantial reductions in IOP and medication burden not

only in mild to moderate glaucoma cases, but also in subjects who were previously using multiple topical medications or had undergone prior glaucoma surgeries."

The full published article is available here. Certain data from this study were presented previously at ophthalmic conferences in the United States and Europe.

Glaukos 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® Trabecular Micro-Bypass Stent,* in 2012 and approved its second-generation *iStent inject* device 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 the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South Africa.

"This study underscores the potential for *iStent inject* to be a viable alternative to glaucoma patients' chronic use of topical medications, which often require complex dosing regimens, have multiple side effects and can be ineffective due to high rates of non-adherence," said Thomas Burns, Glaukos president and chief executive officer. "Our fundamental goal is to transform glaucoma therapy by providing ophthalmic surgeons and their patients a comprehensive set of MIGS technologies designed to safely and effectively manage IOP across the full range of glaucoma progression and severity."

Glaukos is pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy products, all of which are investigational in the United States.

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 primary open-angle glaucoma, 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 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 safety and efficacy of our products, as might be suggested in the published research referenced above, and the extent to which the additional MIGS surgical and sustained pharmaceutical therapy products we are developing receive applicable regulatory approval or are commercialized in the United States or internationally. 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, 2018 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.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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