# International Study Confirms Significant, Sustained IOP and Medication Reduction Following Standalone Implantation of Glaukos' iStent inject® in Glaucoma Patients with Substantial Disease Burden

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*iStent inject Achieved 42% Reduction in Mean IOP to 14.6 mmHg and 82% Reduction in Mean Medications to 0.55 at 3 Years Postoperative with Favorable Safety Profile in Real-World Cohort*

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 independent, international study published in *Advances in Therapy* showed standalone implantation of the *iStent inject*® *Trabecular Micro-Bypass System* in eyes with substantial glaucoma disease burden achieved a 42% reduction in mean intraocular pressure (IOP) to 14.6 mmHg and an 82% reduction in mean medications to 0.55 at three years postoperative.

This prospective, consecutive case series of 44 eyes was conducted to evaluate the long-term outcomes of the two-stent *iStent inject* system as a sole procedure in predominantly primary open-angle glaucoma subjects with considerable disease burden. The cohort's preoperative mean IOP was 25.3 mmHg on a mean of 2.98 ocular hypotensive medications, with 75% of eyes on three to five medications and no eyes medication-free. Moreover, 50% of eyes had a history of prior glaucoma surgery.

All *iStent inject* procedures were performed by Fritz H. Hengerer, MD, PhD at an academic ophthalmology center in Heidelberg, Germany. Additional results of eyes with three-year follow-up showed:

- Mean IOP ≤ 18 mmHg was achieved by 97% of eyes vs. 9.1% preoperatively ($p<0.0001$), and mean IOP ≤ 15 mmHg was achieved by 70% of eyes vs. 2.3% preoperatively ($p<0.0001$).
- IOP decreased ≥ 20% vs. preoperative measurements in 88% of eyes.
- Sixty-one percent of eyes were medication free and all eyes maintained or decreased their three-year medication burden vs. preoperative levels.
- The safety profile was favorable, with minimal adverse events and stable corrected distance visual acuity reported.

“The results of this study highlight the profound efficacy and safety profile of *iStent inject* as a sole procedure in a glaucoma patient population with substantial disease burden,” said Dr. Hengerer, the study’s author. “Of particular note is the very high portion of eyes – 97% – that achieved IOP at or below 18 mmHg at three years postoperative. This finding is key to our fundamental clinical goal of preserving glaucoma patients’ vision because reaching this IOP threshold is known to be associated with lessened visual field decline.”

Certain data from this study have been presented previously at professional ophthalmic meetings in the United States and Europe. The full article in *Advances in Therapy* may be accessed online here.

“While *iStent inject* has been studied primarily in patients with mild-to-moderate open-angle glaucoma, Dr. Hengerer’s results add to an emerging body of evidence suggesting that our multiple-stent technology may also be a viable option for patients with more advanced disease, including those who have undergone prior surgeries,” said Thomas Burns, Glaukos president and chief executive officer. “Results like these further strengthen our resolve to advance our strategy to provide ophthalmic surgeons and their patients a comprehensive suite of injectable, micro-scale solutions capable of addressing a full range of glaucoma progression and disease states.”

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS), which involves insertion of a micro-scale device from within the eye's anterior chamber through a small corneal incision. Glaukos MIGS devices are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor. In 2012, Glaukos received U.S. Food and Drug Administration (FDA) approval and launched its first MIGS device, the *iStent® Trabecular Micro-Bypass Stent*.

The company’s second-generation MIGS device, the *iStent inject Trabecular Micro-Bypass System*, was approved by the FDA in June 2018. The *iStent inject* includes two stents preloaded in an auto-injection mechanism that allows an ophthalmic surgeon to inject stents into multiple locations of the trabecular meshwork through a single corneal incision. The *iStent inject* has also been approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore, South Africa and other international markets. Glaukos is also pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy pipeline 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 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 well as the potential applications 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 and our Quarterly Report on Form 10-Q for the first quarter ended March 31, 2019. 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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