



## Pivotal Trial Results for Glaukos' iStent inject® Published in Leading Ophthalmic Journal

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*Study Published in Ophthalmology Demonstrates Significant, Sustained Clinical Benefit and Confirms Favorable Safety Profile for Next-Generation Device Approved by FDA in June 2018*

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 the U.S. Investigational Device Exemption (IDE) pivotal trial results for its next-generation *iStent inject*® Trabecular Micro-Bypass System have been published in *Ophthalmology*.

Results of the *iStent inject* prospective, randomized, controlled, multicenter clinical trial, which included 505 mild-to-moderate primary open-angle glaucoma (POAG) subjects from 41 investigational sites, formed the basis for Food & Drug Administration approval of the device in June 2018. In the study, 387 subjects were randomized to *iStent inject* in combination with cataract surgery and 118 subjects were randomized to cataract surgery only. Subjects were followed through 24 months with annual medication washouts.

The *iStent inject* met the study's primary and secondary effectiveness endpoints as follows:

- At 24 months, 75.8% of the *iStent inject* cohort achieved a 20% or greater reduction in unmedicated diurnal intraocular pressure (DIOP), compared to 61.9% for the cataract-only cohort ( $p = 0.005$ ).
- At 24 months, the mean reduction in unmedicated DIOP was 7.0 mmHg for the *iStent inject* cohort, compared to 5.4 mmHg for the cataract-only cohort ( $p < 0.001$ ).

Through 24 months, the overall safety profile of *iStent inject* was highly favorable, with the rate of adverse events for *iStent inject* in combination with cataract surgery similar to cataract surgery alone.

Additional key findings highlighted in the *Ophthalmology* article include:

- At 24 months, observed data show that the *iStent inject* cohort achieved a 31% reduction in mean observed unmedicated DIOP to 17.1 mmHg from an unmedicated baseline DIOP of 24.8 mmHg.
- At 24 months, observed data show that 63.2% of the *iStent inject* cohort achieved unmedicated mean DIOP at or below 18 mmHg, compared to 50.0% for the cataract-only cohort.
- At 23 months, observed data show that the *iStent inject* cohort achieved a 75% reduction in the mean number of medications, compared to 47% for the cataract-only cohort.

- At 23 months, of the responders, 84% of treatment eyes were medication free, compared to 67% of the control eyes.

“These published results reinforce the performance and safety of *iStent inject*, which now offers ophthalmic surgeons an important new treatment option for effectively managing IOP in glaucoma patients while potentially reducing or eliminating the need for topical hypotensive medications,” said Thomas W. Samuelson, MD, a surgeon at Minnesota Eye Consultants and Adjunct Professor at the University of Minnesota, as well as trial investigator and author of the *Ophthalmology* article. “The results of the U.S. IDE pivotal trial, along with the expanding library of peer-reviewed clinical evidence, confirm that *iStent inject* combined with phacoemulsification provides predictable, clinically significant IOP reductions and an excellent safety profile through an elegant, micro-invasive procedure with minimal tissue disruption.”

“Publication of the *iStent inject* pivotal study in a leading ophthalmic journal represents an important milestone for Glaukos,” said Thomas Burns, Glaukos president and chief executive officer. “We continue to be encouraged with the U.S. ophthalmic community’s response to *iStent inject*. Surgeon feedback and emerging real-world results in the U.S. mirror our experience in international markets and continue to provide us with high confidence in the product’s prospects and what it means for glaucoma surgeons and their patients.”

Glaukos commenced a U.S. commercial launch of *iStent inject* in September 2018. The product is also commercially available in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore, South Africa and other international markets.

The *iStent inject* is designed to optimize the natural physiological outflow of aqueous humor by creating two patent bypasses through the trabecular meshwork, the main source of resistance in glaucomatous eyes, resulting in multi-directional flow through Schlemm’s canal. It includes two heparin-coated titanium stents preloaded into an auto-injection system that allows the surgeon to precisely implant stents into two trabecular meshwork locations through a single corneal entry point in a straightforward click-and-release motion. The *iStent inject* is the company’s next-generation trabecular micro-bypass technology and is based on the same fluidic method of action as the company’s first-generation pioneering *iStent*<sup>®</sup> *Trabecular Micro-Bypass Stent*, which has been implanted in more than 450,000 eyes worldwide since its introduction in 2012 and has earned a reputation of demonstrated efficacy with an excellent safety profile. Each *iStent inject* stent is approximately 0.23 mm x 0.36 mm, or about one-third the size of the first-generation *iStent*. The company believes the *iStent inject* is the smallest medical device ever approved by the FDA.

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  $\geq 2$  lines  $\geq 3$  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](http://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 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  $\geq 1$  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](http://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 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.com](http://www.glaukos.com) or at [www.sec.gov](http://www.sec.gov). In addition, information about the risks and benefits of our products is available on our website at [www.glaukos.com](http://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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