

# International Study Demonstrates Potential for Titratable Treatment with 1, 2 or 3 Glaukos iStent<sup>®</sup> Trabecular Micro-Bypass Stents in Open-Angle Glaucoma Patients

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Results of 119-Subject Study Published in *Clinical Ophthalmology* Showed Incremental Reduction in IOP and Medications with Use of Additional Stents

LAGUNA HILLS, 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 a new international study, published in the December 2015 issue of **Clinical Ophthalmology**, showed that patients achieved significantly greater reduction in intraocular pressure (IOP) at 18 months with use of each additional iStent<sup>®</sup> Trabecular Micro-Bypass Stent. These results demonstrate the potential of implanting one or more iStents as titratable therapy to achieve different levels of IOP reduction.

In this prospective, randomized study conducted by multiple surgeons at a single investigational site, 119 subjects with open-angle glaucoma and preoperative unmedicated IOP between 22 mmHg and 38 mmHg received one, two or three iStents in a standalone procedure. In this study design, selection for the number of stents was based on randomization and not on each glaucoma patient's specific needs. The study design included a primary efficacy endpoint of =20% IOP reduction at 12 months from baseline unmedicated IOP without use of prescription eye drops or secondary glaucoma procedures. The secondary efficacy endpoint was IOP =18 mmHg at 12 months without use of prescription eye drops or secondary glaucoma procedures.

Approximately 89%, 90% and 92% of the one-, two- and three-stent groups met the primary and secondary endpoints, respectively. Importantly, nearly two-thirds of patients on single stent therapy alone achieved postoperative pressures of  $\leq 15$  mmHg without medication at 12 months. Moreover, at 18 months, mean unmedicated IOP was 15.9 mmHg, 14.1 mmHg and 12.2 mmHg in the one-, two- and three-stent groups, respectively. No intraoperative ocular adverse events occurred and safety data were similar across all stent groups. By month 18, four eyes had undergone cataract surgery due to progression of cataract.

“The results of this study underscore not only the significant IOP-lowering capability of a single iStent in a standalone procedure, but also the benefit of using additional iStents to achieve even greater levels of sustained IOP reduction with reduced reliance on prescription eye drops,” said L. Jay Katz, MD, director of the Glaucoma Service at the Wills Eye Hospital and professor of ophthalmology at Thomas Jefferson University in Philadelphia. “The results demonstrate the future role and potential of multiple-stent implantation as titratable glaucoma therapy, allowing surgeons to tailor their treatments depending on the patient’s particular disease severity and progression.”

Sponsored by Glaukos, this study was intended to comparatively assess one, two and three stents as a sole therapy in open-angle glaucoma patients, and is believed to be the first ever ophthalmic medical device study to randomize subjects to receive single versus multiple surgical devices. It is designed for five-year postoperative follow-up.

Made of heparin-coated titanium, the iStent is inserted through a small corneal incision and placed into Schlemm’s canal, a circular channel in the eye that collects aqueous humor and eventually delivers it into the bloodstream. If the aqueous humor cannot drain appropriately through the trabecular meshwork and Schlemm’s canal, the pressure within the eye (IOP) can become elevated. Once inserted, the iStent restores the natural outflow pathways for aqueous humor and provides sustained IOP reduction.

The iStent is approved in the European Union and certain other international markets for use either in combination with cataract surgery or as a standalone procedure in phakic and pseudophakic eyes. In the United States, the iStent 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.

Glaukos’ product portfolio also includes the iStent inject® Trabecular Micro Bypass Stent, which relies on a similar method of action as iStent but features two stents preloaded in an auto-inject mechanism. It is already approved for commercial use in the European Union, Canada and Australia, and an initial commercial launch of iStent inject is currently underway in Germany. Glaukos is conducting U.S. IDE clinical trials for two versions of the iStent inject, one in combination with cataract surgery and another for use as a standalone procedure in glaucoma patients who are not undergoing concurrent cataract surgery.

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. According to Market Scope, more than 80 million people worldwide have glaucoma, including approximately 4.3 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.5 million people in the United States.

## 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 = 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 company focused on the development and commercialization of breakthrough products and procedures 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. These include statements about our plans, objectives, strategies and prospects regarding, among other things, the safety and efficacy of our current products, the efficacy of implanting one or more iStents as titratable therapy, and our ability to secure regulatory approvals for pipeline technologies. 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 are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission (SEC), including our most recent Quarterly Report on Form 10-Q. 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 these forward-looking statements, 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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