



International Study Shows Long-Term Titrated IOP Control with 1, 2 or 3 Glaukos iStent® Trabecular Micro-Bypass Stents in Open-Angle Glaucoma Patients

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Latest Findings Published in Clinical Ophthalmology Reveal 30% to 43% Reductions in Unmedicated Mean IOP for Single or Multiple iStent Implantations at 36 Months Postoperative

SAN CLEMENTE, 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, according to a study published in *Clinical Ophthalmology*, implantation of one, two or three *iStent*® Trabecular Micro-Bypass Stents achieved mean unmedicated intraocular pressure (IOP) reductions of 30%, 37% and 43%, respectively, at 36 months postoperative.

In this prospective, randomized study conducted by multiple surgeons at a single investigational site, 119 open-angle glaucoma (OAG) subjects with preoperative unmedicated IOP of 22 mmHg to 38 mmHg received one, two or three *iStents* in a standalone procedure. At approximately 36 months postoperative, the one-, two- and three-stent groups achieved unmedicated (post-washout) mean IOP of 17.4 mmHg, 15.8 mmHg and 14.2 mmHg, respectively, compared to preoperative unmedicated mean IOP of 25.0 mmHg for the one- and two-stent groups and 25.1 mmHg for the three-stent group. At 42 months, 61%, 91% and 91% of eyes in the one-, two- and three-stent groups, respectively, achieved a $\geq 20\%$ reduction in IOP without medication.

"The latest results of this ongoing study further underscore the durable and substantial IOP-lowering and medication-reducing effects of one or multiple *iStents* in mild-to-moderate glaucoma patients," said L. Jay Katz, MD FACS, who co-authored the study. Dr. Katz is the director of Glaucoma Service at the Wills Eye Hospital and is Glaukos chief medical officer. "Moreover, the study's findings corroborate the data of prior laboratory investigations and clinical studies, making clear that the most significant portion of the IOP reduction results from implantation of the first stent, with each additional stent providing additional incremental benefits."

According to the study authors, no intraoperative or perioperative complications were reported. During 42 months of postoperative follow-up, the most commonly reported adverse event was progression of pre-existing cataract. However, no eyes required additional glaucoma surgery.

The full article is available [here](#). Outcomes in this study through 18 months were published in 2015 by *Clinical Ophthalmology*. Study subjects will continue to be followed for a total of 60 months.

“At Glaukos, we have long believed in the potential to titrate MIGS technologies in order to effectively manage glaucoma patients’ IOP based on their specific clinical needs,” said Thomas Burns, Glaukos president and chief executive officer. “While the indication for our current *iStent* device is for implantation of a single stent in mild-to-moderate glaucoma patients undergoing cataract surgery, these latest study results help to illustrate the value of ultimately providing surgeons a comprehensive array of single- and multi-stent MIGS devices designed to address a full range of glaucoma disease states and progression.”

Glaukos is the study sponsor and the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS. The company’s *iStent* was approved by the U.S. Food & Drug Administration (FDA) in 2012. Inserted through a small corneal incision made during cataract surgery, the *iStent* is designed to reduce IOP in mild-to-moderate OAG patients by restoring the natural physiological outflow of aqueous humor through the trabecular meshwork and into Schlemm’s canal, the eye’s primary drainage channel. Glaukos is currently pursuing FDA approvals for five additional MIGS surgical and sustained pharmaceutical therapy pipeline products:

iStent inject[®] *Trabecular Micro-Bypass System*, which is designed for use during cataract surgery and allows a surgeon to inject stents into two trabecular meshwork locations through a single corneal entry point. The *iStent inject* is approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South America.

iStent[®] *SA Trabecular Micro-Bypass System*, which is a standalone, two-stent procedure that is similar to the *iStent inject* and designed to reduce IOP in pseudophakic, mild-to-moderate OAG eyes.

iStent infinite[™] *Trabecular Micro-Bypass System*, which is a standalone, three-stent procedure, designed to reduce IOP in refractory OAG patients.

iStent Supra[®] *Suprachoroidal Micro-Bypass Stent*, which is designed to reduce IOP by accessing the eye’s suprachoroidal space and is approved in the European Union.

iDose[™] *Travoprost*, which is an implant containing a special formulation of travoprost, a prostaglandin analog used to reduce IOP. Implanted during a micro-invasive procedure, the *iDose Travoprost* is designed to continuously elute therapeutic levels of the medication from within the eye for extended periods of time. When depleted, it can be removed and replaced in a similar, subsequent procedure. 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. 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 OAG, the most common form of the disease.

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 OAG 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 postoperative adverse events reported in the randomized pivotal trial included early postoperative corneal edema (8%), BCVA loss of ≥ 1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%), early postoperative anterior chamber cells (3%), and early postoperative 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 company focused on the development and commercialization of breakthrough products and procedures 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*, 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. 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 ability of our products to achieve outcomes consistent with those detailed in the study referenced in this release and our ability to secure acceptance from the U.S. FDA for our next-generation pipeline products and to successfully commercialize them. 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, 2017 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.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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