



iStent® Trabecular Micro-Bypass Stent Reduced IOP and Medication Use in Predominately Hispanic Glaucoma Patient Population, According to Published Study

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Case Series in Clinical Ophthalmology Reported Mean IOP of 12.9 mm Hg and 61% Reduction in Mean Medication Burden 1 Year Following iStent Implantation in Conjunction with Cataract Surgery

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 a study of 134 predominantly Hispanic eyes with open-angle glaucoma (OAG), published in *Clinical Ophthalmology*, showed mean intraocular pressure (IOP) of 12.9 mm Hg and a 61% decrease in mean medication burden one year following implantation of the *iStent® Trabecular Micro-Bypass Stent* in combination with cataract surgery.

The retrospective, consecutive case series includes 168 eyes of 128 patients who underwent *iStent* implantation with concomitant cataract surgery, of which 134 eyes in 100 patients have been followed through one year. Study researchers reported that 87% of subjects had moderate to severe OAG and 80% were Hispanic, a population segment with a higher-than-average incidence and prevalence of OAG. Up to 21% of Hispanics are expected to develop OAG by age 80, according to a reference cited in the study.

All procedures in the series were performed by Mark J. Gallardo, MD, at a single site in El Paso, Texas. Before surgery, patients were placed into three subgroups in accordance with the surgeon's typical clinical practice and based on the patient's IOP level, medication burden and treatment goal. In the 134 eyes with one-year postoperative follow-up, the safety profile was favorable and treatment success was achieved in all three subgroups as follows:

Group 1: Comprised of 65 eyes with controlled IOP on at least one ocular hypotensive medication preoperatively and a treatment goal to reduce medication burden while maintaining IOP control. One year following the procedure, medication burden decreased from a mean of 2.4 medications preoperatively to 0.6 at one year; this decrease was statistically significant ($p < 0.001$). Further, mean IOP decreased to 12.7 mm Hg, compared to 13.6 mm Hg preoperatively.

Group 2: Comprised of 31 eyes with IOP not controlled on up to two ocular hypotensive medications

preoperatively and a treatment goal to reduce IOP and maintain or reduce medication burden. One year following the procedure, all eyes had IOP of 18 mm Hg or lower with a statistically significant ($p < 0.001$) reduction to a mean IOP of 12.6 mm Hg, compared to 19.1 mm Hg preoperatively. Medication burden decreased to a mean of 0.4 medications, compared to 1.1 preoperatively.

Group 3: Comprised of 40 eyes on three or more ocular hypotensive medications and/or uncontrolled IOP preoperatively with a treatment goal to reduce IOP in order to avoid filtering surgery. One year following the procedure, 95% (38 of 40 eyes) achieved their treatment goal. In these 38 eyes, mean IOP decreased to 13.6 mm Hg, compared to 19.3 mm Hg preoperatively, which was statistically significant ($p < 0.001$). Medication burden decreased to a mean of 1.8 medications, compared to 3.2 preoperatively.

“These data show that *iStent* in combination with cataract surgery can effectively reduce IOP and topical ocular hypotensive medication use in a mainly Hispanic patient population, including those with more advanced disease,” said Dr. Gallardo. “Importantly, these results were achieved in a real-life clinical setting, where the treatment goals differ by patient, based on their individual needs and disease state. The study’s high success rate overall and within each patient subgroup underscores the tangible benefits of using trabecular bypass stenting to manage IOP and medication burden in a demographically diverse glaucoma patient population.”

The full *Clinical Ophthalmology* article is available online at <https://www.dovepress.com/outcomes-of-combined-trabecular-micro-bypass-and-phacoemulsification-i-peer-reviewed-article-OPHTH>.

Typically associated with elevated IOP, glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. It is a leading cause of blindness. According to Market Scope, more than 80 million people worldwide have glaucoma, including 4.5 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.6 million people in the United States.

The *iStent* was approved by the U.S. Food & Drug Administration (FDA) in June 2012 and 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. The *iStent* is inserted through the trabecular meshwork and into Schlemm’s canal, the eye’s drainage system, where it restores the natural, physiological outflow of aqueous humor. Made of surgical-grade non-ferromagnetic titanium that is coated with heparin, the *iStent* is approximately 1.0 mm long and 0.33 mm wide. Glaukos believes it is the smallest medical device ever approved by the FDA.

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 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 continued efficacy of our products as might be suggested in the study described 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 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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