



# International Study Shows Two Glaukos iStent® Trabecular Micro-Bypass Stents and One Topical Medication Deliver Sustained IOP Reduction

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*86% of Eyes Had IOP  $\leq$  18 mm Hg at Three Years Postoperative, According to Results Published in Clinical Ophthalmology*

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 published in [Clinical Ophthalmology](#) showed that two *iStent® Trabecular Micro-Bypass Stents* and one topical ocular hypotensive medication achieved a 38% reduction in mean medicated intraocular pressure (IOP) three years following surgery in 37 phakic eyes. Phakic refers to eyes that have not undergone prior cataract surgery and still have a natural lens.

This prospective study, conducted at a single international site, enrolled patients with open-angle glaucoma (OAG) not controlled on two topical medications and with unmedicated IOP of 22-38 mm Hg. All patients in the study received two *iStents* in a standalone procedure, and began daily use of topical travoprost one day after surgery. Through three years, 86% of eyes achieved IOP  $\leq$  18 mm Hg. Mean medicated IOP in these eyes decreased to 14.0 mm Hg on one medication, versus 22.4 mm Hg on two medications preoperatively. The safety profile was favorable with no intraoperative or device-related adverse events reported.

These three-year results update 18-month data from the same study that was published in 2014 in the *Journal of Cataract and Refractive Surgery*. In that publication, follow-up through 18 months showed a decrease in medicated IOP to 14 mm Hg or less on one medication, versus 22.2 mm Hg on two medications preoperatively. Study researchers plan to continue to follow patients through five years postoperative.

"The three-year data demonstrate the long-term performance and safety of trabecular bypass stents and topical travoprost in subjects with OAG not controlled on two medications," said David F. Chang, MD, who authored the *Clinical Ophthalmology* article. "In addition, our results support the hypothetical synergy of using trabecular stents to increase outflow through the conventional aqueous fluid pathway while also using a prostaglandin analog such as topical travoprost to increase outflow through the uveoscleral, or unconventional, pathway."

Glaukos is the study sponsor and the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS.

The *iStent* was approved by the U.S. Food & Drug Administration in 2012 and is the industry's flagship MIGS device. Inserted through the trabecular meshwork and into Schlemm's canal via a small corneal incision made during cataract surgery, the *iStent* is designed to restore the natural, physiological outflow of aqueous fluid through the conventional pathway and reduce IOP. The company also is pursuing FDA approval of two versions of its next-generation *iStent inject*® *Trabecular Micro-Bypass* device: one for use in combination with cataract surgery and another for use in a standalone procedure. The *iStent inject* is designed to deploy two stents into separate trabecular meshwork locations and is being evaluated in FDA clinical trials for IOP reduction. The company also is pursuing FDA approval of a third MIGS device, the *iStent SUPRA*, which accesses the uveoscleral pathway for aqueous humor outflow.

"Our fundamental goal is to transform glaucoma therapy by providing ophthalmic surgeons and their patients a full complement of micro-scale glaucoma technologies that deliver sustained reductions in IOP and topical medication use," said Thomas Burns, Glaukos president and chief executive officer. "Study results like these help to strengthen our view that future glaucoma therapy may ultimately involve use of multiple stents and multiple pathways for aqueous fluid outflow to manage patients' IOP and disease progression."

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 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.

#### **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  $\geq 1$  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 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*<sup>®</sup>, 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 limitations, the continued efficacy of our products as might be suggested in the study described herein; the extent to which the company will be able to obtain regulatory approval for its next-generation products; and the extent to which the company's next-generation products will obtain an indication of use for multiple stents and multiple pathways for aqueous fluid outflow. 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, 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](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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