

# International Study Shows 3-Year Benefits of Glaukos iStent® Trabecular Micro-Bypass Stent in Combination with Cataract Surgery

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Study in Journal of Cataract and Refractive Surgery Reveals 36% Reduction in Mean IOP and 86% Reduction in Mean Number of Medications in Patients with Range of Glaucoma Type and Progression

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 clinical study, published in the **Journal of Cataract and Refractive Surgery**, showed use of the iStent® Trabecular Micro-Bypass Stent in conjunction with cataract surgery provided a 36% reduction in mean intraocular pressure (IOP) and an 86% reduction in the mean number of glaucoma medications three years following surgery.

The prospective, open-label, non-randomized study was conducted at the Eye Clinic Marienplatz in Munich, Germany by Medical Director Tobias H. Neuhann, MD. The goal was to assess the long-term postoperative outcomes of one iStent implanted during cataract surgery in subjects with primary open-angle glaucoma, pseudoexfoliation glaucoma, secondary or post-traumatic glaucoma or ocular hypertension. There was no preoperative medication washout period and 40% of eyes had undergone previous glaucoma surgeries, primarily laser procedures.

In the study, a single iStent was implanted through the same incision used for cataract surgery in a consecutive series of 62 eyes of 43 subjects. In 39 eyes followed through three years, the mean IOP at three years was 14.9 mmHg, compared to a mean preoperative IOP of 23.4 mmHg. In the same 39 eyes, the mean number of glaucoma

medications used three years following surgery declined to 0.3, compared to a mean of 1.9 medications at subjects' preoperative visits. No operative complications occurred during the cataract surgical procedure or during the stent implantation procedure. Over the three-year follow-up period, five secondary surgeries, two postoperative ocular sequelae and two non-ocular adverse events were reported.

"These data show that implantation of a single iStent in conjunction with micro-incisional cataract surgery provided a sustained reduction in IOP and medication burden with favorable safety through three years postoperative for this patient population with moderate and varied types of glaucoma," said Dr. Neuhann. "In the study, the decision to implant the iStent was based on the wish of the patient to reduce or possibly eliminate the burden of topical glaucoma medications and the intention to offer a surgical treatment for glaucoma with a favorable safety profile. We did not qualify subjects based on specific inclusion or exclusion criteria. Consequently, the population studied in this series was representative of a European clinician's real-world experience with a typical patient group."

In the European Union, the iStent is indicated for reducing IOP in patients diagnosed with primary open-angle glaucoma, pseudoexfoliative glaucoma and pigmentary glaucoma. In Europe, the device can be implanted when combined with cataract surgery in patients who require IOP reduction and/or who would benefit from glaucoma medication reduction. It can also be implanted as standalone treatment for those patients who continue to have elevated IOP despite prior medical treatment or conventional glaucoma surgery. 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. In addition, in the United States, the safety and efficacy of the iStent has not been established in patients with prior glaucoma surgery of any type.

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 intraocular pressure is the only proven treatment. According to Market Scope, more than 80 million people worldwide have glaucoma, including 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.

The iStent was approved by the U.S. Food & Drug Administration (FDA) in June 2012 and is currently approved in more than 20 countries worldwide. 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](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 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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