



New Study Underscores Ability of iStent® Trabecular Micro-Bypass Stent to Achieve Sustained Reductions in IOP and Medication Use in Glaucoma Patients Undergoing Cataract Surgery

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Study in Clinical Ophthalmology Reveals Mean IOP of 15.17 mm Hg and 56% Reduction in Mean Glaucoma Medications 2 Years Following iStent Implantation in Combination 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 published in *Clinical Ophthalmology* showed that a consistent cohort of 107 open-angle glaucoma (OAG) eyes receiving the *iStent® Trabecular Micro-Bypass Stent* in combination with cataract surgery achieved a 22% reduction in mean intraocular pressure (IOP) to 15.17 mm Hg and a 56% reduction in mean ocular hypotensive medications to 0.61 two years following surgery.

The retrospective, consecutive case series includes 350 eyes that underwent *iStent* implantation with concomitant cataract surgery between October 2012 and December 2015. Study researchers reported a favorable safety profile and postoperative follow-up of all eyes is ongoing. All procedures were performed by John P. Berdahl, MD, at a single site in Sioux Falls, South Dakota. The series represents Dr. Berdahl's typical clinical use of the *iStent*. In this study, OAG subjects were defined as patients with primary OAG, normal tension glaucoma and ocular hypertension, with no cases excluded.

"Our data show that mild-to-moderate OAG patients receiving a single *iStent* with cataract surgery can achieve sustained IOP levels approaching 15 mm Hg and also reduce their dependence on glaucoma medications," said Dr. Berdahl. "These outcomes are important because controlling IOP is the only proven treatment for glaucoma and its management is often hindered by the poor compliance, cost and side effects associated with topical ocular hypotensive medications that patients must administer one or more times a day for the rest of their lives."

Study researchers indicated that, to their knowledge, this study represents the largest sample size published to date regarding the *iStent* in combination with cataract surgery. The full *Clinical Ophthalmology* article is available online at <https://www.dovepress.com/clinical-evaluation-of-a-trabecular-microbypass-stent-with-phacoemulsi-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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