International Study Shows Sustained Reduction in Intraocular Pressure through Three Years with Two Glaukos iStent® Trabecular Micro-Bypass Stents in Phakic and Pseudophakic Glaucoma Patients

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Results Published in Clinical Ophthalmology Reveal Sustained, Safe Reduction in IOP to ≤ 15 mmHg Without Medication through 36 Months

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 study, published in the November 2015 issue of *Clinical Ophthalmology*, showed that two *iStent® Trabecular Micro-Bypass Stents* provided "statistically significant, sustained and safe reduction in intraocular pressure (IOP) to ≤ 15 mmHg without medication through 36 months" in patients with open-angle glaucoma.

In this prospective pilot study conducted by multiple surgeons at a single investigational site, 39 phakic and pseudophakic subjects with open-angle glaucoma and preoperative unmedicated IOP between 22 mmHg and 38 mmHg received two stents in a standalone procedure. At 36 months, subjects not taking medication achieved mean IOP of 15.2 mmHg, representing a 37% reduction from unmedicated baseline IOP. In four subjects who required medication, IOP ranged from 13 mmHg to 15.7 mmHg at 36 months. There were no postoperative adverse events related to stent implantation, except for one incidence of early postoperative hyphema that resolved at one week.

"Our study shows that sustained IOP reduction to 15 mmHg is possible after implantation of multiple *iStent* devices in a standalone procedure," said Eric D. Donnenfeld, MD, Ophthalmic Consultants of Long Island. "Of particular note is that the IOP reduction in these patients was accomplished without concomitant cataract surgery, showing that the efficacy of *iStents* is significant and separate from the IOP reduction associated with cataract surgery. Moreover, nearly 90% of patients in the study were medication free three years following the procedure. Because glaucoma management is often a challenge due to the poor compliance and side effects associated with topical medications, a safe and effective stent procedure that enables sustained reduction in IOP may be a preferable alternative to glaucoma patients and their physicians."

This is the first Micro-Invasive Glaucoma Surgery (MIGS) study to evaluate long-term outcomes through three years for implantation of two *iStent* devices as a standalone treatment for patients with open-angle glaucoma. The study is designed for follow-up through five years.

The *iStent* is approved in the European Union and certain other international markets for use either in combination with cataract surgery or as a standalone procedure in phakic and pseudophakic eyes. 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.

Glaukos' product portfolio also includes the *iStent inject® Trabecular Micro Bypass Stent*, which relies on a similar method of action as *iStent* but features two stents preloaded in an auto-inject mechanism. It is already approved for commercial use in the European Union, Canada and Australia, and an initial commercial launch of *iStent inject* is currently underway in Germany. Glaukos is conducting U.S. IDE clinical trials for two versions of the *iStent inject*, one in combination with cataract surgery and another for use as a standalone procedure in glaucoma patients who are not undergoing concurrent cataract surgery.

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 approximately 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.

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 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 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 and future products, and our *iStent inject*® pipeline technology and corresponding efforts to secure regulatory approvals. 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. Therefore, they may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this presentation. 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. The known risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission (SEC) and available in the Investor section of our website at www.glaukos.com or at www.sec.gov.

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