New International Study Highlights IOP-Lowering Performance of Glaukos iStent inject® Trabecular Micro-Bypass in Standalone Procedure

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One Year Following iStent inject Implantation, 57 Phakic Eyes with Open-Angle Glaucoma Achieved ≥ 20% Reduction in IOP vs. Preoperative Unmedicated IOP

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 in a study published in *Advances in Therapy,* 100% of 57 phakic eyes with open-angle glaucoma achieved a ≥ 20% reduction in unmedicated intraocular pressure (IOP) one year after implantation of the *iStent inject® Trabecular Micro-Bypass* in a standalone procedure. Phakic refers to eyes that have not undergone prior cataract surgery and have a natural lens.

The *iStent inject* is a second-generation Micro-Invasive Glaucoma Surgery (MIGS) device that includes two stents preloaded into an auto-injection mechanism. It allows an ophthalmic surgeon to inject the stents from within the eye's anterior chamber through the trabecular meshwork and into Schlemm's canal, the eye's drainage canal. Once in place, the stents are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor.

The study was conducted at a single international site, where 11 surgeons performed the 57 *iStent inject* procedures. Study researchers reported a high safety profile and plan to follow subjects through five years. Additional study findings at one year postoperative included:

- All eyes had IOP ≤ 18 mm Hg and 67% of eyes had IOP ≤ 15 mm Hg without medication vs. preoperative unmedicated IOP between 22-38 mm Hg.
- Mean unmedicated IOP was 14.2 mm Hg, a 42% reduction from preoperative mean unmedicated IOP of 24.4 mm Hg; this reduction was maintained through 18 months.

"Our data suggest that second-generation trabecular stents, implanted as a sole procedure, can achieve sustained IOP and medication reductions in open-angle glaucoma patients," said Richard Lindstrom, MD, who authored the study. "These outcomes are promising because they underscore the potential for *iStent inject* to be a viable alternative to open-angle glaucoma patients' chronic use of topical ocular hypotensive medications, which often require complex dosing regimens, have multiple side effects and can be ineffective due to high rates of non-compliance."

The *iStent inject* uses the same fluidic mechanism of action as the first-generation *iStent® Trabecular*

Micro-Bypass, which was approved by the U.S. Food & Drug Administration (FDA) in 2012 for use in conjunction with cataract surgery. 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. The *iStent inject* is approximately one-third the size of *iStent* and is for investigational use only in the United States, with two IDE clinical trials underway for two versions of the product, one for use in conjunction with cataract surgery and another for use as a standalone procedure.

In the European Union and Canada, *iStent inject* is approved for use either in combination with cataract surgery or as a standalone procedure. It is also approved for use in combination with cataract surgery in Australia.

The full *Advances in Therapy* article is available online at here.

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.

About *iStent Trabecular Micro-Bypass (U.S.)*

Indication for Use: The *iStent Trabecular Micro-Bypass* 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 and the extent to which we may obtain regulatory approval for any of the products discussed herein. 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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