Glaukos iStent® Trabecular Micro-Bypass Stent Reduced IOP and Lowered Medication Burden in Patients with Severe Glaucoma, According to New Study

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Combined with Cataract Surgery, iStent Achieved Mean Postoperative IOP of 14.1 mm Hg and 28% Reduction in Mean Medication Use in 32 Eyes Followed for 36 Months Postoperative

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 the January 2018 issue of the Journal of Glaucoma showed that a single *iStent® Trabecular Micro-Bypass Stent* implanted during cataract surgery in patients with severe open-angle glaucoma achieved mean postoperative intraocular pressure (IOP) of 14.1 mm Hg and a 28% reduction in the mean number of glaucoma medications used after 36 months of follow-up.

The retrospective case series included 59 glaucomatous eyes with cataracts and severe visual field loss. At baseline, the medicated mean IOP was 19.3 mm Hg and the mean number of topical glaucoma medications used per eye was 2.3. In 49 eyes followed for 24 months after *iStent* implantation and concomitant cataract surgery, mean postoperative IOP decreased to 14.9 mm Hg while the mean number of glaucoma medications used per eye declined to 1.6. In a consistent cohort of 32 eyes with available data through three years postoperative, the IOP reduction was maintained. At three years, this cohort achieved a mean postoperative IOP of 14.1 mm Hg, from a baseline mean medicated IOP of 18.1 mm Hg, and a 28% reduction in mean glaucoma medications used per eye from 2.44 preoperatively to 1.75.

“While many prior studies have documented the clinical benefits of combining *iStent* implantation with cataract surgery in glaucoma patients who are in the mild to moderate stage of the disease, we believe this is the first published study to focus on its use in severe glaucoma patients undergoing cataract surgery,” said John Berdahl MD, a South Dakota-based ophthalmic surgeon and one of the article’s authors. “Our study showed that severe glaucoma patients experienced sustained reductions in IOP and medication use through three years postoperative.”

According to the study authors, no intraoperative complications were noted. Among the 59 eyes in the

series, four required additional surgery.

Glaukos is the study sponsor and the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS. The company's *iStent* was approved by the U.S. Food & Drug Administration (FDA) in 2012. Inserted through a small corneal incision made during cataract surgery, the *iStent* is designed to reduce IOP by restoring the natural physiological outflow of aqueous humor through the trabecular meshwork and into Schlemm's canal, the eye's primary drainage channel.

"Although the *iStent* is currently indicated for use in the United States during cataract surgery in mild to moderate glaucoma patients, this study offers important insights into the potential for our technology platform to ultimately serve a full range of glaucoma disease states and progression," said Thomas Burns, Glaukos president and chief executive officer.

Glaukos announced recently that it has submitted an Investigational Device Exemption application to the FDA, seeking authorization to study its *iStent infinite™ Trabecular Micro-Bypass System*. The *iStent infinite* is designed for use as a standalone procedure to reduce IOP in refractory or severe glaucoma patients. It includes three trabecular bypass stents preloaded into an auto-injection system that allows the surgeon to inject stents across a span of five to six clock hours around Schlemm's canal.

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. Based on analysis of population-based surveys, medical claims data and other statistics, the company estimates that there are approximately 5.4 million people in the U.S. with primary open-angle glaucoma, the most common form of the disease.

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 mm Hg or greater than 36 mm Hg 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 ability of our products to achieve outcomes consistent with those detailed in the study referenced in this release and our ability to secure acceptance from the U.S. FDA of expanded indications for our products to include severe glaucoma or to commence a clinical trial or gain U.S. regulatory approval or market acceptance for the *iStent infinite*. 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 September 30, 2017 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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