Glaukos' iStent inject® Delivers Greater IOP Reduction vs. iStent® According to Newly Published Case Series

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While Both iStent and iStent inject Showed Significant IOP and Medication Reduction in Combo-Cataract Procedures at 1 Year Postoperative, iStent inject Achieved Greater Absolute IOP Declines with 93% of Subjects Medication-Free vs. 76% of iStent Subjects

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, announced today that an independent, international case series published in *Ophthalmology and Therapy* showed that *iStent inject® Trabecular Micro-Bypass System* achieved a greater absolute intraocular pressure (IOP) reduction and a higher medication-free rate at one year postoperative, compared to the first-generation *iStent® Trabecular Micro-Bypass Stent*. All subjects in the case series received stents in combination with cataract surgery.

This real-world retrospective case series included 137 eyes with cataract and mild-to-moderate glaucoma or ocular hypertension. More than 73% of eyes in both groups were in early states of glaucoma disease progression and approximately 22% had prior glaucoma surgery. All procedures were performed by David Manning, MD, at a single practice in Australia. Consecutive patients received either *iStent inject* (n=70) or *iStent* (n=67), based on availability in the Australian market.

At one year postoperative, mean IOP in eyes receiving *iStent inject* decreased 1.8 mmHg more than iStent eyes, based on the decrease in absolute IOP for each group. In addition, 92.9% of *iStent inject* eyes were medication-free at one-year postoperative, vs. 76.1% for the iStent eyes. The safety profile was favorable in both groups, with few adverse events and no secondary glaucoma surgeries.

"This case series represents one of the first and largest datasets to compare performance of *iStent* and *iStent inject* in the hands of a single surgeon and underscores the ability of both devices to effectively reduce IOP and medication burden in a procedure with an excellent safety profile," said Dr. Manning, a glaucoma surgeon at the Hunter Cataract and Eye Centre in Charleston, South Australia. "Even though the study was not designed for prospective comparison, it highlights the added benefit and peace of mind *iStent inject* can offer surgeons and patients in terms of reliably managing IOP."

The full article in *Ophthalmology and Therapy* may be accessed online here.

Glaucoma is characterized by progressive, irreversible vision loss caused by optic nerve damage. There

is no cure for the disease. However, by reducing the eye pressure, the only proven effective treatment, vision may be stabilized. 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.

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS), which involves insertion of a micro-scale device from within the eye's anterior chamber through a small corneal incision. Glaukos' MIGS devices are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor. The trabecular meshwork is the site of greatest resistance to outflow in glaucomatous eyes. Glaukos received U.S. Food and Drug Administration (FDA) approval for its first-generation MIGS device, the *iStent*, in 2012. Its second-generation *iStent inject,* which received FDA approval in 2018, includes two stents preloaded in an auto-injection mechanism that facilitates stent insertion into multiple trabecular meshwork locations through a single corneal incision. The *iStent inject* is also approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore, South Africa and other international markets. Glaukos is pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy pipeline products, all of which are investigational in the United States.

"Dr. Manning's real-world experience makes clear that *iStent* and *iStent inject* both succeed in lowering IOP, with the *iStent inject* offering some meaningful advantages," said Thomas Burns, Glaukos president and chief executive officer. "The *iStent inject* provides surgeons enhanced procedural ease and facilitates creation of two distinct, multi-directional outflow pathways, designed to reduce IOP and the need for topical glaucoma medications, which have troubling side effects and persistently high non-adherence rates. The elegance and predictability of *iStent inject* represents yet another Glaukos innovation designed to tackle important unmet clinical needs with novel surgical or sustained pharmaceutical solutions for people suffering with glaucoma, corneal disorders and retinal diseases."

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

Indication for Use: The *iStent inject Trabecular Micro-Bypass System* Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate primary open-angle glaucoma.

Contraindications: The *iStent inject* is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber angle, retrobulbar tumor, thyroid eye disease, or 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 congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

MRI Information: The *iStent inject* is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the *iStent inject* have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents.

Adverse Events: Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent inject vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%).

Caution: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

For more information, visit www.glaukos.com.

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 and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. 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 launched its next-generation *iStent inject*® device in the United States in September 2018. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

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 and safety profile of our products, as well as the potential applications of our products as might be suggested in the published research referenced 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and our Quarterly Report on Form 10-Q for the first quarter ended June 30, 2019. Our filings with the Securities and Exchange Commission are available in the Investor Section of our website at www.glaukos.comor 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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