



Glaukos Announces FDA Approval for the iStent inject® Trabecular Micro-Bypass System

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Next-Generation Device from MIGS Pioneer Offers Ophthalmic Surgeons a Compelling New Treatment Option for Managing Glaucoma Patients' IOP

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on the development and commercialization of novel surgical devices and sustained pharmaceutical therapies designed to transform the treatment of glaucoma, today announced it has received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for the *iStent inject® Trabecular Micro-Bypass System* indicated for the reduction of intraocular pressure (IOP) in adult mild-to-moderate primary open-angle glaucoma (POAG) patients undergoing concomitant cataract surgery.

The *iStent inject* is designed to optimize the natural physiological outflow of aqueous humor by creating two patent bypasses through the trabecular meshwork, the main source of resistance in glaucomatous eyes, resulting in multi-directional flow through Schlemm's canal. It includes two heparin-coated titanium stents preloaded into an auto-injection system that allows the surgeon to precisely implant stents into two trabecular meshwork locations through a single corneal entry point in a straightforward click-and-release motion. The *iStent inject* is the company's next-generation trabecular micro-bypass technology and is based on the same fluidic method of action as the company's first-generation pioneering *iStent®*, which has been implanted in more than 400,000 eyes worldwide since its introduction in 2012 and has earned a reputation of demonstrated efficacy and safety. Each *iStent inject* stent is approximately 0.23 mm x 0.36 mm, or about one-third the size of the first-generation *iStent*. The company believes the *iStent inject* is the smallest medical device ever approved by the FDA.

"U.S. ophthalmic surgeons have been eagerly awaiting the availability of *iStent inject*, which offers them an exciting new treatment option for effectively managing glaucoma patients' IOP while potentially reducing or eliminating the need for topical hypotensive medications," said Thomas W. Samuelson, MD, a surgeon at Minnesota Eye Consultants, Adjunct Professor at the University of Minnesota and an investigator in the U.S. *iStent inject* pivotal trial. "The results of the U.S. trial, along with those of numerous international peer-reviewed studies, confirm that *iStent inject* provides predictable, clinically significant IOP reductions with an excellent safety profile through an elegant, micro-invasive procedure with minimal tissue disruption."

The FDA approval is based on the *iStent inject* U.S. IDE pivotal study, a prospective, randomized, multicenter clinical trial that included 41 investigational sites and 505 mild-to-moderate POAG eyes

that were randomized to receive *iStent inject* in combination with cataract surgery (n=387) or cataract surgery only (n=118.) The pivotal trial data show that the *iStent inject* achieved a statistically significant reduction in unmedicated diurnal IOP in patients undergoing cataract surgery at 24 months as 75.8% of the *iStent inject* cohort achieved a 20% or greater reduction in unmedicated IOP and the mean unmedicated IOP reduction was 7.0 mmHg for the *iStent inject* cohort. In addition to meeting the study's primary and secondary effectiveness endpoints, at 24 months, observed data show that the *iStent inject* cohort achieved a 31% mean reduction, or 7.7 mmHg, in unmedicated IOP from an unmedicated mean baseline IOP of 24.8 mmHg to 17.1 mmHg. Finally, through 24 months, the overall rate of adverse events for the *iStent inject* cohort was similar to cataract surgery alone.

"The approval of *iStent inject* represents another major Glaukos milestone in the pursuit of our mission to transform glaucoma therapy and further strengthens our position at the forefront of micro-scale innovation," said Thomas Burns, Glaukos president and chief executive officer. "We greatly appreciate the diligent work of the FDA to conduct a thorough and timely review of the *iStent inject* and grant approval. In addition, we are very grateful to the investigators and patients who participated in the clinical trial and played an instrumental role in helping us to bring *iStent inject* to the U.S. Given its clinical performance and enhanced procedural elegance, we believe the *iStent inject* will be an attractive, two-stent solution for U.S. ophthalmic surgeons to reliably manage glaucoma patients' IOP in a straightforward and effective manner."

Following the completion of various administrative matters with the FDA, the company intends to commence initial commercial launch activities later in the third quarter.

The *iStent inject* is already commercially available in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South Africa, where, in aggregate, more than 30,000 *iStent injects* have been implanted.

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS). In addition to the *iStent inject*, the company is currently pursuing FDA approval for four additional MIGS surgical and sustained pharmaceutical therapy pipeline products, all of which are investigational in the U.S., designed to address the full range of glaucoma disease stage and severity.

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 OAG, the most common form of the disease.

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 \geq 2 lines \geq 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 Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on the development and commercialization of novel surgical devices and sustained pharmaceutical therapies 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 inject*, measuring 0.23 mm wide and 0.36 mm long, 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 extent to which the *iStent inject* will be accepted as a new treatment option for effectively managing glaucoma patients' IOP; risks related to our implementation of a strategic U.S. commercial launch of *iStent inject*, such as risks associated with product pricing, marketing and sales efforts. 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 March 31, 2018 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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