



IDE Pivotal Trial Results for Glaukos' iStent inject® Show Significant Reductions in Unmedicated IOP in Glaucoma Subjects Undergoing Cataract Surgery

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iStent inject Data Presented at ASCRS Annual Meeting Demonstrate Primary and Secondary Effectiveness Endpoints Met with Overall Favorable Safety Profile through 24 Months

SAN CLEMENTE, Calif. & WASHINGTON--(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 two-year U.S. Investigational Device Exemption (IDE) pivotal trial data showed that its *iStent inject*® Trabecular Micro-Bypass System achieved a statistically significant reduction in unmedicated diurnal intraocular pressure (IOP) in patients undergoing cataract surgery.

Results of the *iStent inject* prospective, randomized, multicenter clinical trial, which included 41 investigational sites and 505 open-angle glaucoma (OAG) subjects, were presented today at the American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting by Thomas W. Samuelson, MD, an ophthalmic surgeon at Minnesota Eye Consultants. In the study, 387 subjects were randomized to *iStent inject* in combination with cataract surgery and 118 subjects were randomized to cataract surgery only. Subjects were followed through 24 months with annual medication washouts.

The *iStent inject* met the study's primary and secondary effectiveness endpoints as follows:

- At 24 months, 75.3% of the *iStent inject* cohort achieved a 20% or greater reduction in unmedicated IOP, compared to 61.9% for the cataract-only cohort.
- At 24 months, the mean unmedicated IOP reduction was 6.9 mmHg for the *iStent inject* cohort, compared to 5.4 mmHg for the cataract-only cohort.

Through 24 months, the overall rate of adverse events for the *iStent inject* in combination with cataract surgery was similar to cataract surgery only. While not part of the effectiveness claims being pursued by the company, additional key findings include:

- At 24 months, observed data show that the *iStent inject* cohort achieved a 31% mean reduction in unmedicated (post-washout) IOP to 17.1 mmHg from an unmedicated (post-washout) mean baseline IOP of 24.8 mmHg.
- At 24 months, observed data show that 62.6% of the *iStent inject* cohort achieved unmedicated mean IOP at or below 18 mmHg, compared to 49.2% for the cataract-only cohort.
- At 23 months, observed data show that the *iStent inject* cohort achieved a 75% reduction in the

mean number of medications, compared to 47% for the cataract-only cohort.

The *iStent inject* is designed to improve aqueous humor outflow into Schlemm's canal and reduce IOP in mild-to-moderate OAG patients undergoing cataract surgery. It includes two heparin-coated titanium stents preloaded into an auto-injection system that allows the surgeon to inject stents into multiple trabecular meshwork locations through a single corneal entry point. The *iStent inject* relies on the same fluidic method of action as the company's first-generation *iStent*[®] *Trabecular Micro-Bypass Stent*, which was approved by the U.S. Food and Drug Administration (FDA) in 2012 and has been shown to lower IOP in adult cataract patients with mild-to-moderate OAG. Each *iStent inject* stent is approximately 0.23 mm x 0.36 mm, or about one-third the size of *iStent*, which the company believes is the smallest medical device ever approved by the FDA.

The *iStent inject* is not approved for use in the U.S. Glaukos submitted a pre-market approval application for the *iStent inject* to the FDA in December 2017. The *iStent inject* is commercially available in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South Africa.

"The IOP-lowering capability of a single *iStent* in combination with cataract surgery has been well documented in the clinical literature, while various published studies and real-world international experience have also shown that multiple *iStent* devices can provide incremental IOP-lowering benefits," said Thomas Burns, Glaukos president and chief executive officer. "Given its performance and enhanced ease-of-use, we believe the *iStent inject*, if approved by the FDA, will be an attractive, two-stent option for U.S. ophthalmic surgeons to reliably manage glaucoma patients' IOP in a straightforward and effective manner."

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.:

iStent[®] *SA Trabecular Micro-Bypass System*, which is a standalone, two-stent procedure that is similar to the *iStent inject* and designed to reduce IOP in pseudophakic, mild-to-moderate OAG eyes.

iStent infinite[™] *Trabecular Micro-Bypass System*, which is a standalone, three-stent procedure, designed to reduce IOP in refractory OAG patients.

iStent Supra[®] *Suprachoroidal Micro-Bypass Stent*, which is designed to reduce IOP in mild-to-moderate OAG subjects undergoing cataract surgery by accessing the eye's suprachoroidal space. This device is approved in the European Union.

iDose[™] *Travoprost*, which is an implant containing a special formulation of travoprost, a prostaglandin analog used to reduce IOP. Implanted during a micro-invasive procedure, the *iDose Travoprost* is designed to continuously elute therapeutic levels of the medication from within the eye for extended periods of time.

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.

All educational content of the ASCRS•ASOA Annual Meeting is planned by its program committee, and ASCRS•ASOA does not endorse, promote, approve or recommend the use of any products, devices or services.

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 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, our ability to secure U.S. regulatory approval for the *iStent inject* and our other pipeline products and the extent to which the *iStent inject* and our other pipeline products obtain market acceptance. 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 2017 Annual Report on Form 10-K 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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Source: Glaukos Corporation

For Glaukos Corporation

Media Contact:

Cassandra Dump

(619) 971-1887

cassy@pascalecommunications.com

or

Investor Contact:

Chris Lewis

Director, Investor Relations, Corporate Development & Strategy

(949) 481-0510

clewis@glaukos.com