



Glaukos Products to be Subject of Multiple Presentations at American Academy of Ophthalmology Annual Meeting

2019-10-09

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 its products will be included in various presentations at the American Academy of Ophthalmology ([AAO](#)) annual meeting, which begins Saturday, October 12, 2019 at the Moscone Center in San Francisco, CA.

Key presentations include:

Saturday, October 12

ePoster Discussion: Glaucoma
1:00-2:00 pm PDT, Station 2

- PO170: Long-Term Outcomes of Trabecular Bypass Stenting with Cataract Surgery with Rates of Progression of Visual Fields and Optical Coherence Tomography (OCT)
Author: Richard A. Lehrer MD
- PO172: *iStent inject*[®] Trabecular Bypass with or without Cataract Surgery for Glaucoma: Four-Year Prospective, Consecutive Case Series
Author: Fritz H. Hengerer MD
- PO173: Prospective Randomized Study Evaluating One, Two or Three Standalone Trabecular Micro-Bypass Stents (*iStent*[®]) for Open-Angle Glaucoma (OAG): Five-Year Outcomes
Author: Daniel Lee MD

Additional e-Posters and Videos (Viewable at terminals throughout AAO)

- PO216: One-Year Results of Trabecular Micro-Bypass Stent Implantation (*iStent* or *iStent inject*) in a Real-World Setting
Author: Ricardo A. Paletto Guedes MD
- PO219: Trabecular Micro-Bypass Stent Implantation with Cataract Surgery in Pseudoexfoliative Glaucoma: Long-Term Results
Authors: Tanner J Ferguson MD; Russell J. Swan MD

- PO220: Sustained IOP and Medication Reduction with *iStent inject* Trabecular Bypass Stents in OAG: Four-Year Outcomes
Author: Jason Bacharach MD
- V20: *iStent inject*: Tips and Tricks
Author: Andrew J. Tatham MBChB
- V23: Walking on the Moon: A Perspective on Trabecular Micro-Bypass Surgery for the Cataract Surgeon
Author: Ricardo A. Paletta Guedes MD

Glaukos will be exhibiting on the showroom floor throughout AAO at booth #2238.

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. 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.

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* have 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 surgeon poster presentations 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 second 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.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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