Combining Implantation of Glaukos iStent inject® Trabecular Micro-Bypass with Topical Travoprost Provides Sustained IOP Reduction and Favorable Safety Profile, According to New Study

2017-06-21

After 18 Months of Follow-up, Mean IOP Declined 35% to 12.9 mm Hg

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 of 53 open-angle glaucoma subjects recently published in *Clinical & Experimental Ophthalmology* showed that the *iStent inject® Trabecular Micro-Bypass*, combined with topical travoprost, delivered a 35% reduction in mean intraocular pressure (IOP) to 12.9 mm Hg after 18 months of follow-up.

All subjects enrolled in this prospective, international study had open-angle glaucoma not controlled on two preoperative topical medications. The preoperative medicated mean IOP was 19.7 mm Hg. One day after implantation of two *iStent inject* stents in a standalone procedure, all subjects began a regimen of topical travoprost, which is a commonly prescribed ocular hypotensive medication. A total of 11 surgeons performed the procedures and no device-related adverse events occurred through 18 months. In addition:

- At 12 months, 91% of eyes achieved a ≥ 20% decrease in IOP with the reduction of one medication.
- At 12 months, 100% of eyes achieved IOP ≤ 18 mm Hg, and 87% of eyes achieved IOP ≤ 15 mm Hg, with the reduction of one medication.
- Following medication washout at 13 months, mean unmedicated IOP decreased 33% to 16.6 mm Hg, versus 24.9 mm Hg preoperatively.

“The results of this study underscore the viability of using *iStent inject* together with a single postoperative prostaglandin medication to consistently manage IOP to levels in the 15 mm Hg range,” said John Berdahl MD, who authored the article. “What’s more, the study washouts show the independent capability of *iStent inject* to significantly lower IOP without any benefit from topical medications. This is important because we know that glaucoma patients often don’t adhere to topical medication treatment regimens.”

Glaukos is the study sponsor and the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS. The company’s flagship MIGS device, the *iStent® Trabecular Micro-Bypass Stent,* 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 conventional pathway.

Glaukos' next-generation *iStent inject* device is designed to deploy two stents into separate trabecular meshwork locations for enhanced IOP reduction and procedural ease. Two versions of the *iStent inject* – for combination-cataract and standalone indications – are currently being evaluated in FDA clinical trials for IOP reduction. The *iStent inject* is approved for use in the European Union, Canada, Australia, Brazil and Singapore.

Glaukos is also evaluating a Travoprost Intraocular Implant with the *iDose*™ delivery system in a Phase II Investigational New Drug (IND) trial. Implanted during a micro-invasive procedure, the *iDose* is designed to continuously elute therapeutic levels of a proprietary formulation of travoprost for extended periods of time. Travoprost is designed to increase outflow primarily through the uveoscleral, or unconventional, pathway, and to a lesser extent through the conventional pathway. When the implant's medication is depleted, the implant can be removed and replaced in a similar micro-invasive procedure.

"These results add to the growing body of peer-reviewed data that demonstrate the power of multiple trabecular bypass stents to control IOP and reduce patients' reliance on topical medications," said Thomas Burns, Glaukos president and chief executive officer. "Moreover, this study helps to illustrate the advantages of harnessing both the conventional and unconventional outflow pathways in order to effectively manage IOP in glaucoma patients."

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. According to Market Scope, more than 80 million people worldwide have glaucoma, including 4.5 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.6 million people in the United States.

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 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 limitations, the continued efficacy of our products as might be suggested in the study described herein; the extent to which the company will be able to obtain regulatory approval for its next-generation products; and the extent to which the company's next-generation products will obtain an indication of use for multiple stents and multiple pathways for aqueous fluid outflow. 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 2016 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170621005212/en/

Source: Glaukos Corporation

Glaukos Corporation

Media Contact:

Cassandra Dump

(619) 971-1887

cassy@pascalecommunications.com

or

Investor Contact:

Sheree Aronson

VP, Investor Relations

(949) 367-9600 ext 371

saronson@glaukos.com