



International Study Shows Favorable 3-Year Results of 2 Glaukos iStent® Trabecular Micro-Bypass Stents as Initial Treatment for Naïve Glaucoma

2016-09-22

Newly Diagnosed Primary Open-Angle Glaucoma Patients Who Received 2 iStents Achieved 43% Reduction in Mean Intraocular Pressure through 36 Months Following Standalone Surgery

LAGUNA HILLS, 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 an international study published in the current issue of *Ophthalmology and Therapy* showed that newly diagnosed primary open-angle glaucoma patients achieved a 43% reduction in mean intraocular pressure (IOP) to 14.6 mm Hg through 36 months following implantation of two *iStent® Trabecular Micro-Bypass* stents in a standalone procedure.

In this prospective study conducted by multiple ophthalmic surgeons at a single investigational site, 101 phakic subjects with primary open-angle glaucoma that had not undergone prior glaucoma treatment of any kind were randomized in a 1:1 ratio to receive either two iStents in a standalone procedure or topical ocular hypotensive medication therapy (travoprost). Phakic refers to eyes that have not undergone prior cataract surgery and contain a natural lens. The study is designed for follow-up of all subjects through five years. Through 36 months, study results showed:

- Mean IOP in the stent group (n=39) declined 43% from 25.5 mm Hg to 14.6 mm Hg, while mean IOP in the travoprost group (n=34) declined 39% from 25.1 mm Hg to 15.3 mm Hg.
- 11% of eyes in the stent group required additional topical medication therapy, compared to 23% in the travoprost group.
- 91% of eyes in the stent group had IOP \leq 18 mm Hg without additional topical medication therapy, compared to 79% of eyes in the travoprost group; 62% of eyes in the stent group had IOP \leq 15 mm Hg without additional topical medication therapy, compared to 21% of eyes in the travoprost group.

"We embarked on this study to assess the potential utility of *iStent* as an initial treatment in naïve open-angle glaucoma patients versus topical travoprost, which is a commonly prescribed first-line medication therapy," said Steven D. Vold, MD. "Three-year safety and efficacy data are promising and show that two *iStents* achieved sustained IOP reduction, with fewer subjects requiring additional topical medication therapy compared to topical travoprost. These results indicate that *iStent* implantation as initial therapy in newly diagnosed glaucoma patients may be a viable alternative to topical ocular hypotensive medications, which are often associated with high rates of non-compliance, side effects

and/or ocular surface damage.”

The article may be accessed online at <http://link.springer.com/article/10.1007%2Fs40123-016-0065-3>.

Approved by the U.S. Food & Drug Administration (FDA) in 2012, *iStent* is indicated for use in the United States 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. The *iStent* is the industry's first Micro-Invasive Glaucoma Surgery (MIGS) device. It is inserted from within the anterior chamber through the trabecular meshwork and into the eye's drainage canal, known as Schlemm's canal, where it is designed to restore the natural physiological outflow of aqueous humor. Made of surgical-grade non-ferromagnetic titanium that is coated with heparin, the *iStent* is approximately 1.0 mm long and 0.33 mm wide. Glaukos believes it is the smallest medical device ever approved by the FDA.

The company's next-generation MIGS device, the *iStent inject*® *Trabecular Micro-Bypass Stent* includes two stents preloaded in an auto-injection mechanism that allows an ophthalmic surgeon to inject stents into multiple trabecular meshwork locations through a single corneal entry point. The *iStent inject* has been approved in the European Union, Australia and Canada. The *iStent inject* is for investigational use only in the United States, with two IDE clinical trials underway for two versions of the product, one for use in conjunction with cataract surgery and another for use as a standalone procedure.

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 limitation, our ability to receive additional approvals of our products, including, without limitation, the *iStent inject*[®] *Trabecular Micro-Bypass Stent*, by the FDA and other regulatory bodies; and the continued efficacy of our products as might be suggested in the international study described 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 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

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