



Study Reveals Potential Cost Efficiency of Using Two Glaukos iStent® Trabecular Micro-Bypass Stents to Treat Elevated IOP in Glaucoma Patients

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According to Analysis Published in Journal of Medical Economics, Cumulative Cost at Five Years was Lowest for Two-Stent Procedure, Compared to Laser Treatment or Topical Medication Only

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 an analysis published in the *Journal of Medical Economics* evaluating various options for treating elevated intraocular pressure (IOP) in open-angle glaucoma patients showed that two *iStent® Trabecular Micro-Bypass Stents* had a lower projected average cumulative cost at five years than either selective laser trabeculoplasty (SLT) or topical glaucoma medication only.

The population-based, annual state-transition, probabilistic, cost-of-care model used in the analysis was designed to assess direct costs for three treatment options – two *iStents*, SLT or topical medication only – over a five-year time horizon. A clinician panel provided treatment strategy change probabilities and direct costs for drugs, procedures and complications that were included in the analysis.

According to the study authors, the projected average cumulative cost at five years was \$4,420 for the two-stent procedure, compared to \$4,730 for SLT and \$6,217 for topical medication only. The model showed that while the two-stent procedure had the highest initial year cost, it also had the lowest annual marginal cost for each subsequent year. Over the same time period, costs in each year following SLT or topical medication only were more than double that of the two-stent procedure.

“While numerous international studies have shown the ability of two trabecular meshwork stents to effectively control IOP in open-angle glaucoma patients, this analysis is the first to reveal the potential cost efficiency of trabecular stenting, especially over longer time horizons,” said John P. Berdahl, MD, a South Dakota-based ophthalmic surgeon and one of the authors of the *Journal of Medical Economics* article. “Our research indicates that the two-stent treatment option may reduce glaucoma-related health resource use and contribute to direct cost savings, particularly when compared to topical medication only, which is the most commonly used treatment option today but is often ineffective due to high rates of patient non-compliance.”

Glaukos is the study sponsor and the pioneer of Micro-Invasive Glaucoma Surgery, or MIGS. MIGS involves insertion of a micro-scale device from within the eye’s anterior chamber through a small

corneal incision. MIGS devices are designed to reduce intraocular pressure by restoring the natural outflow pathways for aqueous humor. In 2012, Glaukos received U.S. Food & Drug Administration (FDA) approval for the *iStent*, which is implanted in conjunction with cataract surgery and has been shown to lower IOP in adult patients with mild-to moderate open-angle glaucoma.

The company also is pursuing FDA approval of two versions of its next-generation *iStent inject*® *Trabecular Micro-Bypass* device: one for use in combination with cataract surgery and another for use in a standalone procedure. The *iStent inject* is designed to deploy two stents into separate trabecular meshwork locations and is being evaluated in FDA clinical trials for IOP reduction. The *iStent inject* is approved for use in the European Union, Canada, Australia, Singapore and Brazil. The company also is pursuing FDA approval of a third MIGS device, the *iStent SUPRA*, which accesses the uveoscleral pathway for aqueous humor outflow.

“Our core strategy is to provide a full complement of micro-scale treatment options that can effectively manage IOP and overcome many of the drawbacks of conventional therapies,” said Thomas Burns, Glaukos president and chief executive officer. “Peer-reviewed study results like these help to illustrate the potential for our technologies to offer important clinical and economic benefits for physicians, patients and the healthcare system.”

The full *Journal of Medical Economics* article is available [here](#).

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 and cost efficiency 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.

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