



# Glaukos Announces Submission of Pre-Market Approval Application for the iStent Inject® Trabecular Micro-Bypass

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*Second-Generation Device Designed to Reduce IOP in Cataract Patients with Glaucoma*

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 it has submitted a pre-market approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the *iStent inject® Trabecular Micro-Bypass Stent*.

The *iStent inject* is designed to improve aqueous humor outflow into Schlemm's canal and reduce intraocular pressure (IOP) in mild-to-moderate open-angle glaucoma 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.

"This PMA submission marks a significant milestone for Glaukos as we continue to deliver our deep pipeline of novel glaucoma surgical devices and sustained pharmaceuticals," said Thomas Burns, president and chief executive officer. "The *iStent inject* represents the first in a series of five new products we are expecting to introduce over the next five years, culminating in what we believe will be the industry's broadest portfolio of technologies designed to address the full range of glaucoma disease states and progression."

The *iStent inject* prospective, randomized, multicenter clinical trial included 41 sites and 505 randomized subjects who received either *iStent inject* in combination with cataract surgery or cataract surgery alone. The *iStent inject* met its primary effectiveness endpoint in the trial, which was a 20% or greater reduction in IOP from baseline at 24 months. The company plans to release efficacy and safety data from the trial sometime in the first half of 2018.

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 FDA in 2012 and has been shown to lower IOP in adult cataract patients with mild-to-moderate open-angle glaucoma. 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 currently approved for use in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South Africa.

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 open-angle glaucoma, the most common form of the disease.

### **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  $\geq 1$  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](http://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*<sup>®</sup>, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 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](http://www.glaukos.com) or at [www.sec.gov](http://www.sec.gov). In addition, information about the risks and benefits of our products is available on our website at [www.glaukos.com](http://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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