



Glaukos Corporation Announces Completion of Patient Enrollment in U.S. Pivotal Clinical Trial for iStent inject®

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Company Achieves Randomization Goal of 500 Patients

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 the completion of patient enrollment in its U.S. Food and Drug Administration (FDA) pivotal Investigational Device Exemption (IDE) trial for the *iStent inject*® *Trabecular Micro-Bypass Stent*.

The *iStent inject* relies on a similar fluidic method of action as the company's flagship *iStent*® *Trabecular Micro-Bypass Stent*, which was approved by the FDA in 2012 and has been shown to lower intraocular pressure in adult cataract patients with mild-to-moderate open-angle glaucoma. The *iStent inject* is comprised of a micro-needle that is preloaded with two stents and driven by an auto-inject mechanism for predictable and facile implantation. The *iStent inject* is designed to enable ophthalmic surgeons to inject stents into multiple trabecular meshwork locations through a single corneal entry point. The *iStent inject* is approximately one-third the size of *iStent*, which Glaukos believes is the smallest device ever approved by the FDA.

The *iStent inject* prospective, randomized, multicenter clinical trial includes approximately 40 sites and 500 randomized subjects. Subjects in the trial are randomized to either *iStent inject* in combination with cataract surgery or cataract surgery alone. The study protocol calls for randomized subjects to be followed for two years, with a primary endpoint of a 20% or greater reduction in intraocular pressure from baseline. The results of the trial are expected to form the basis for the company's future Pre-Market Approval (PMA) submission to the FDA.

"Glaukos has pioneered the new Micro-Invasive Glaucoma Surgery market and clinical class and is dedicated to transforming glaucoma therapy for patients worldwide," said Thomas Burns, president and CEO of Glaukos. "Our completion of the *iStent inject* U.S. pivotal trial patient enrollment and the achievement of our patient randomization goal marks another milestone towards introducing breakthrough technologies that can advance glaucoma patient care."

The *iStent inject* is already approved for commercial use in the European Union and Australia, and Glaukos is currently conducting an initial commercial launch of *iStent inject* in Germany.

In addition to conducting an *iStent inject* U.S. IDE pivotal trial in combined cataract procedures, Glaukos is also conducting an initial U.S. IDE clinical trial to evaluate a second version of the *iStent inject* to be used as a standalone procedure in glaucoma patients who are not undergoing concurrent cataract surgery. The objective of this version of the *iStent inject* is to make micro-scale injectable therapy a viable option for a much larger segment of the patient population with open-angle glaucoma.

The company believes that approximately 20% of the estimated 3.7 million cataract procedures performed annually in the United States are in patients also diagnosed with open-angle glaucoma or ocular hypertension. 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 intraocular pressure is the only proven treatment. According to Market Scope, more than 78 million people worldwide have glaucoma, including 4.2 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.4 million people in the United States.

About *iStent Trabecular Micro-Bypass Stent*

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 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. These include statements about our plans, objectives, strategies and prospects regarding, among other things, our *iStent inject*[®] pipeline technology and corresponding efforts to secure regulatory approvals. 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. Therefore, they may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this presentation. 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 these forward-looking statements, 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. The known risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission (SEC) and available in the Investor section of our website at www.glaukos.com or at www.sec.gov.

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