Glaukos Completes Patient Enrollment in Initial Phase of U.S. IDE Clinical Trial for Standalone Version of iStent inject®

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

The initial phase of the standalone *iStent inject* interventional, randomized, open label, multicenter clinical trial includes approximately 75 subjects randomized to receive either *iStent inject* or laser trabeculoplasty. In this initial phase, subjects will be followed for three months to evaluate safety. The results of the initial phase are expected to form the basis for the company's submission to the FDA for expansion of the trial into the pivotal phase, which will include approximately 425 additional randomized subjects and seek a primary outcome of intraocular pressure (IOP) reduction.

The standalone *iStent inject* features two micro-scale stents preloaded into an auto-injection system that allows an ophthalmic surgeon to inject stents into multiple trabecular meshwork locations through a single, self-sealing corneal entry point. It is designed for use in phakic and pseudophakic open-angle glaucoma patients. Phakic refers to eyes that contain a natural lens, while pseudophakic refers to eyes in which the natural lens has been removed and replaced with an artificial lens.

In addition to the U.S. IDE initial trial to evaluate *iStent inject* in standalone procedures, Glaukos is also conducting a U.S. IDE pivotal trial to evaluate *iStent inject* in conjunction with cataract surgery. Enrollment of approximately 500 subjects in the pivotal combination-cataract trial was completed in mid-2015 and two-year follow-up is set to conclude in mid-2017. Both versions of *iStent inject* rely on a fluidic method of action that is similar to the company's flagship *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. The *iStent inject* stents are approximately one-third the size of the first-generation *iStent,* which Glaukos believes is the smallest medical device ever approved by the FDA.

The *iStent inject* is already approved for commercial use in the European Union, Australia and Canada. In an international study published recently in *Advances in Therapy*, 57 phakic open-angle glaucoma eyes underwent standalone *iStent inject* procedures. At two years postoperative, the *iStent*

inject procedure was shown to reduce unmedicated IOP by 42%, to a mean of 14.2 mm Hg from a preoperative mean of 24.4 mm Hg.

“Glaukos pioneered Micro-Invasive Glaucoma Surgery, or MIGS, to provide new treatment options for glaucoma patients and practitioners,” said Thomas Burns, Glaukos president and chief executive officer. “Completion of enrollment in the initial phase of the standalone *iStent inject* clinical trial marks achievement of an important milestone in our mission to transform glaucoma therapy.”

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, approximately 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 the First-Generation *iStent Trabecular Micro-Bypass Stent,* Approved by FDA in 2012

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. 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, the continued efficacy of our products as might be suggested in the study described above and the extent to which we may obtain regulatory approval for any of the products discussed herein. 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 law.

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