



Glaukos Achieves Pipeline Milestone with Completion of Patient Enrollment in U.S. IDE Trial for *iStent infinite*[™]

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Company Completes Enrollment of Subjects in Trial Designed to Evaluate Safety and Performance of Its Three-Stent System in Standalone Procedure for Advanced Glaucoma

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, today announced the completion of patient enrollment in its U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial for the *iStent infinite*[™] Trabecular Micro-Bypass System.

The *iStent infinite* is designed for use in a standalone procedure to reduce elevated intraocular pressure (IOP) in refractory glaucoma patients. It includes three heparin-coated titanium stents preloaded into an auto-injection system that allows the surgeon to inject stents across a span of five to six clock hours around Schlemm's canal, the eye's primary drainage channel. Once in place, the stents are designed to lower IOP by restoring the natural, physiological outflow of aqueous humor. The *iStent infinite* is similar to the company's two-stent *iStent inject*[®] Trabecular Micro-Bypass System, which was approved by the FDA in June 2018 for the reduction of IOP in adult mild-to-moderate primary open-angle glaucoma patients undergoing concomitant cataract surgery.

The *iStent infinite* prospective, unmasked, multi-center, single-arm clinical trial enrolled subjects who had undergone prior unsuccessful incisional glaucoma surgery and had IOP not adequately controlled with currently tolerated topical ocular hypotensive medications as well as subjects who had not undergone prior incisional glaucoma surgery but were on maximally tolerated topical ocular hypotensive medications with uncontrolled IOP. In the trial, 72 subjects were implanted with the *iStent infinite* at 15 separate clinical sites. All surgeons performing the *iStent infinite* procedures were board-certified glaucoma specialists.

The trial's primary effectiveness endpoint is a 20% or greater reduction in mean diurnal IOP from baseline at 12 months postoperative on the same or fewer topical ocular hypotensive medications. Glaukos plans to use the trial results as the basis for seeking FDA approval of the *iStent infinite*.

"We expeditiously achieved this enrollment milestone due, in part, to the favorable safety profile surgeons experienced with their initial *iStent infinite* subjects, which helped to speed enrollment overall," said Thomas Burns, Glaukos president and chief executive officer. "We appreciate the

commitment and dedication of the clinical investigators, who play a vital role in bringing new innovations to patients suffering with advanced glaucoma disease and at risk for significant vision loss. We look forward to working cooperatively with the FDA as the trial process moves forward, and we continue to target U.S. commercialization of the *iStent infinite*, if approved, by 2021.”

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS), which involves insertion of a micro-scale device from within the eye's anterior chamber through a small corneal incision. Glaukos' MIGS devices are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor. Glaukos received FDA approval for its first-generation MIGS device, the *iStent*, in 2012. Its second-generation *iStent inject*, approved by the FDA in 2018, includes two stents preloaded in an auto-injection mechanism that facilitates stent insertion into multiple trabecular meshwork locations through a single corneal incision. The *iStent inject* is also approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Korea, Singapore and other international markets. Glaukos is pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy pipeline products, all of which are investigational in the United States.

About *iStent inject Trabecular Micro-Bypass System (U.S.)*

Indication for Use: The *iStent inject Trabecular Micro-Bypass System* Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate primary open-angle glaucoma.

Contraindications: The *iStent inject* is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber angle, retrobulbar tumor, thyroid eye disease, or 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 congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

MRI Information: The *iStent inject* is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the *iStent inject* have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents.

Adverse Events: Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for *iStent inject* vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%).

Caution: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

For more information, visit www.glaukos.com.

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* have 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 and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. 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 launched its next-generation *iStent inject*[®] device in the United States in September 2018. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

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 and safety profile of our products, the extent to which we may obtain regulatory approval for the *iStent infinite* or other investigational products, and our ability to successfully commercialize such products. 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 the fiscal year ended December 31, 2018 and our Quarterly Report on Form 10-Q for the second quarter ended June 30, 2019. 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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