



## Glaukos Completes Patient Enrollment in Pivotal Phase of U.S. IDE Clinical Trial for iStent SUPRA®

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*Company Achieves Randomization Goal with 505 Patients*

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 pivotal phase of its U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial for the *iStent SUPRA® Suprachoroidal Micro-Bypass Stent*.

The *iStent SUPRA* prospective, randomized clinical trial includes 36 sites and 505 subjects with mild-to-moderate primary open-angle glaucoma and cataracts. Subjects were randomized to receive either *iStent SUPRA* in combination with cataract surgery or cataract surgery alone. The study has a 24-month primary outcome measure of a 20% or greater reduction in intraocular pressure (IOP) 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.

The *iStent SUPRA* is designed to reduce IOP by accessing the suprachoroidal space in the eye. Also known as the unconventional pathway, this area is responsible for approximately 20% of aqueous fluid outflow. Approximately 4.0 mm in length and curved to follow the eye's anatomy, the *iStent SUPRA* is already approved for marketing in the European Union and certain other countries outside the United States.

"We expect the *iStent SUPRA* to ultimately be an important part of ophthalmic surgeons' armamentarium for effectively managing IOP," said Thomas Burns, Glaukos president and chief executive officer. "Achieving this enrollment milestone represents an important step forward in our goal to provide surgeons and their patients a comprehensive set of options to address a range of glaucoma disease state and progression."

Glaukos pioneered Micro-Invasive Glaucoma Surgery, or MIGS, and introduced the industry's flagship MIGS device, the *iStent® Trabecular Micro-Bypass Stent*, in 2012. The *iStent* accesses the eye's conventional pathway for aqueous humor outflow, which is through the trabecular meshwork and into Schlemm's canal. The company is also conducting FDA clinical trials for two versions of its next-generation *iStent inject® Trabecular Micro-Bypass Stent*, one version to be used in combination with cataract surgery and the other version to be used in a standalone procedure.

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***

**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 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, the continued efficacy of our products and the extent to which we may obtain regulatory approval for any of the products discussed herein; the extent to which the *iStent SUPRA* will meet its primary outcome measure or receive FDA approval; the extent to which the *iStent SUPRA* clinical trial will establish efficacy or safety; and the extent to which the company will be able to achieve its goal of providing glaucoma surgeons and patients a comprehensive set of options to address a range of glaucoma disease states and progression. 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, 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](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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