

# Glaukos Submits IND Application to FDA to Study iDose™ Travoprost Intraocular Implant in Glaucoma Patients

11/19/2015

Company Seeks to Conduct Phase II Clinical Trial to Assess Implant's Safety and Preliminary Efficacy for Reduction of Elevated Intraocular Pressure

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 that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) seeking authorization to study its Travoprost Intraocular Implant with the iDose™ delivery system for investigational use in the reduction of elevated intraocular pressure (IOP) in patients with glaucoma.

Injected through a clear corneal incision and secured in the anterior chamber, the iDose is designed to continuously elute therapeutic levels of medication from within the eye for extended periods of time. The titanium implant is comparable in size to the company's proprietary Micro-Invasive Glaucoma Surgery (MIGS) devices. It is filled with a special formulation of travoprost, a prostaglandin analog used to reduce elevated intraocular pressure. The implant is capped with a membrane that is designed for continuous controlled drug elution into the anterior chamber. When depleted, the implant can be removed and replaced in a similar, subsequent procedure. Glaukos has designed the product to be an alternative to chronic, daily prescription eye drop treatments, which may have high rates of patient non-compliance and cause long-term ocular surface damage to glaucomatous eyes.

"This IND submission represents a seminal milestone, which the Glaukos team achieved well ahead of our original

2016 timeline,” said Thomas Burns, president and CEO of Glaukos. “We believe this micro-scale implant may be a viable answer to the ubiquitous and long-standing problem of patient non-compliance with prescription eye drops and we look forward to working cooperatively with the FDA as they review our IND submission.”

In the IND application, Glaukos proposes to conduct a randomized Phase II clinical trial to assess the safety and preliminary efficacy of two models of the iDose delivery system with different travoprost elution rates compared to topical timolol maleate ophthalmic solution, 0.5%. The Phase II study is proposed to be unmasked at 12 weeks. The IND application includes information on travoprost’s history of safety and efficacy, as well as Glaukos’ preclinical program and early data from an initial international clinical trial on the implant involving 69 patients.

In this initial international study, subjects were randomized to receive either one of two models of the implant, each with different elution rates, or topical travoprost. Through 12 months, mean IOP was lower in the implant groups than in the topical medication group. The results from this initial trial demonstrated that both implant models had a potent IOP-lowering effect and that the implants were generally well-tolerated.

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 approximately 4.3 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.5 million people in the United States.

## 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®, 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, the actions of the FDA with respect to our pending IND application, the initiation and timing of a Phase II clinical study to evaluate the safety and efficacy of the Travoprost Intraocular Implant with the iDose delivery system, and the benefits of our products relative to other glaucoma treatment options. 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, but are not limited to, our ability to advance and complete the proposed clinical trial, our ability to demonstrate the safety and efficacy of the implant in clinical trials, the adequacy of our financial or other resources to pursue continued drug development efforts and our ability to obtain FDA approval of the implant. These and other 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), including our most recent Quarterly Report on Form 10-Q. 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.

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Source: Glaukos Corporation

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**Media Contact:**

Cassandra Dump

(619) 971-1887

**[cassy@pascalecommunications.com](mailto:cassy@pascalecommunications.com)**

or

**Investor Contact:**

Sheree Aronson

VP, Investor Relations

(949) 367-9600 ext 371

**[saronson@glaukos.com](mailto:saronson@glaukos.com)**