Glaukos Will Begin Phase II Clinical Trial for iDose™ Travoprost Intraocular Implant in Glaucoma Patients

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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 the U.S. Food and Drug Administration (FDA) is allowing the company to move forward with activities to begin a U.S. Investigational New Drug (IND) Phase II study of its Travoprost Intraocular Implant with the iDose™ delivery system 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, and capped with a membrane 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 are subject to high rates of patient non-compliance and may cause long-term ocular surface damage in glaucomatous eyes.

The open IND for the Phase II trial follows Glaukos’ recently announced IND submission to the agency in which the company proposed to conduct a randomized trial to assess the safety and preliminary efficacy of two models of the iDose delivery system with different travoprost elution rates compared to a topical timolol maleate ophthalmic solution, 0.5%.
“We are very pleased that the FDA is allowing this trial to begin several months in advance of our original target date,” said Thomas Burns, president and CEO of Glaukos. “We believe the iDose platform has the potential to address important unmet clinical needs by overcoming the significant issue of patient non-compliance with chronic prescription eye drop regimens, and reducing risk of ocular surface damage and other side effects associated with repeated applications of topical drugs.”

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) 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 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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