



Glaukos Completes Patient Enrollment in Phase II Clinical Trial for *iDose*[™] Travoprost Intraocular Implant in Glaucoma Patients

2017-05-03

Company Achieves Randomization Goal of 150 Patients in Trial to Assess Implant's Preliminary Safety and Efficacy for Reduction of Elevated Intraocular Pressure

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 U.S. Investigational New Drug (IND) Phase II study of its Travoprost Intraocular Implant with the *iDose*[™] delivery system in patients with glaucoma.

Implanted during a micro-invasive procedure, the *iDose* is designed to continuously elute therapeutic levels of medication from within the eye for extended periods of time. 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 micro-invasive procedure.

The 150-patient, multi-center, randomized, double-blind Phase II trial will evaluate two models of the *iDose* delivery system with different travoprost elution rates compared to a topical timolol maleate ophthalmic solution, 0.5%. The trial, which will assess preliminary safety and efficacy in lowering intraocular pressure in patients with open-angle glaucoma, will be unmasked after 12 weeks of follow-up, with a topline readout expected later in 2017. Results of the Phase II trial are expected to form the basis for the company's submission to the FDA to conduct expanded Phase III trials on the *iDose* delivery system.

"Our completion of patient enrollment in the *iDose* Phase II trial means that we have achieved an important and timely milestone in our goal to provide glaucoma patients and their physicians a comprehensive set of micro-scale devices and drug-delivery systems that address a full range of glaucoma disease state progression," said Thomas Burns, Glaukos president and chief executive officer. "We believe that the *iDose* delivery system has the potential to overcome many of the drawbacks associated with topical glaucoma medications. We look forward to these initial trial results and to moving towards commencement of Phase III clinical trials to determine the longer-term efficacy of our novel *iDose* delivery system."

Glaukos designed the *iDose* to be an alternative to chronic, daily prescription eye drop therapy, which is subject to high rates of patient non-compliance and may cause long-term ocular surface irritation or damage in glaucomatous eyes. The titanium implant is comparable in size to the company's proprietary Micro-Invasive Glaucoma Surgery (MIGS) devices.

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, 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 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 MIGS to revolutionize the traditional glaucoma treatment and management paradigm. Glaukos launched the *iStent*[®] *Trabecular Micro-Bypass Stent*, 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 discussed herein; the extent to which the clinical trial discussed herein will establish efficacy or safety of the Travoprost Intraocular Implant with the *iDose* delivery system; the extent to which the Travoprost Intraocular Implant with the *iDose* delivery system will meet its future primary outcome measures or receive FDA approval; 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 Annual Report on Form 10-K for 2016. 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.

View source version on
businesswire.com: <http://www.businesswire.com/news/home/20170503005289/en/>

Source: Glaukos Corporation

Glaukos Corporation

Media Contact:

Cassandra Dump

619-971-1887

cassy@pascalecommunications.com

or

Investor Contact:

Sheree Aronson

VP, Investor Relations

949-367-9600 ext 371

saronson@glaukos.com