



Glaukos Corporation's iDose™ Travoprost Achieves Sustained IOP Reduction and Favorable Safety Profile in 12-Month Interim Cohort

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Company Prepares to Commence Phase III U.S. IND Study in First Half of 2018 and Begins Process for iDose Travoprost Regulatory Approval in Europe and Japan

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 that its Travoprost Intraocular Implant with the *iDose*™ delivery system continued to provide sustained reduction in intraocular pressure (IOP) in a 12-month interim cohort of patients in its U.S. Investigational New Drug (IND) Phase II clinical trial.

Implanted during a micro-invasive procedure, the *iDose Travoprost* is filled with a special formulation of travoprost, a prostaglandin analog used to reduce IOP, and designed to continuously elute therapeutic levels of the medication from within the eye for extended periods of time. When depleted, the *iDose Travoprost* can be removed and replaced in a similar, subsequent procedure.

The 154-patient, multi-center, randomized, double-blind Phase II trial was designed to evaluate two models of the *iDose* delivery system with two different travoprost elution rates, compared to topical timolol ophthalmic solution, 0.5% and with a primary efficacy endpoint of non-inferiority to topical timolol. The latest Phase II results are from an available interim cohort of 74 patients, 49 of whom have been implanted with one of the *iDose Travoprost* implant models, with 25 patients in the timolol comparator group. Average IOP reductions observed in this cohort of implant patients during the first 12 months shows that *iDose Travoprost* achieved an approximate 30% reduction in mean IOP vs. baseline IOP. In addition, the mean number of glaucoma medications ranged from 0.54 to 0.56 at 12 months in the fast and slow *iDose Travoprost* elution implant groups, respectively, compared to 0.72 mean medications in the timolol group. The most-recent Phase II data also continued to reveal a favorable safety profile for *iDose Travoprost*, with no adverse events of hyperemia reported to date in either elution group.

Glaukos also announced that the company conducted a productive End-of-Phase II Meeting with the FDA in late 2017 and is currently making preparations to initiate a Phase III IND clinical trial in the first half of 2018. The design of the prospective, randomized, double-blind Phase III *iDose*

Travoprost trial will be similar to the Phase II trial and will enroll approximately 1,000 ocular hypertensive or open-angle glaucoma subjects at clinical sites in the United States and various international locations.

“These latest Phase II results further underscore the potential of *iDose Travoprost* to provide many months of sustained glaucoma pharmaceutical therapy and tackle the significant problem of patient non-adherence to topical medication regimens,” said Thomas Burns, Glaukos president and chief executive officer. “We are pleased to be working cooperatively with the FDA as we prepare for the Phase III trial, which will mark another critical step forward in the advancement of our novel and comprehensive product pipeline designed to transform glaucoma therapy.”

In addition, the company announced today that it has begun the processes to seek regulatory approvals for the *iDose Travoprost* in European markets and in Japan. Today’s announcement is the latest in a series of recent Glaukos pipeline milestone achievements, which also included:

- Planned initiation of U.S. Investigational Device Exemption (IDE) pivotal clinical trial for the *iStent® SA Trabecular Micro-Bypass System*, a standalone, two-stent procedure designed to reduce IOP in pseudophakic, mild-to-moderate open-angle glaucoma patients.
- Submission of the final clinical module of a Pre-Market Approval application to the FDA for the *iStent inject® Trabecular Micro-Bypass System*, a two-stent procedure designed to reduce IOP in mild-to-moderate open-angle glaucoma patients undergoing cataract surgery.
- Submission of an IDE application to the FDA, seeking authorization to study the *iStent infinite™ Trabecular Micro-Bypass System*, a standalone, three-stent procedure, in reducing IOP in refractory open-angle glaucoma patients or those with uncontrolled IOP on maximally tolerated medical therapy.

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. Based on analysis of population-based surveys, medical claims data and other statistics, the company estimates that there are approximately 5.4 million people in the U.S. with primary open-angle glaucoma, the most common form of the disease, and an additional 4.6 million people in the U.S. with ocular hypertension.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed 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. 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, our ability to complete the necessary clinical trials for the *iDose Travoprost*, *iStent SA* and *iStent infinite*, our ability to secure applicable regulatory approval for such products and our other pipeline products and the extent to which any or all of our pipeline products obtain market acceptance. 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, 2017 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 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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