



Glaukos' iDose®TR Demonstrates Sustained IOP Reduction and Favorable Safety Profile Over 36 Months in Phase 2b Study

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Approximately 70% of Subjects were Well-Controlled on iDose TR with the Same or Fewer Topical IOP-Lowering Medications at 36 Months vs. Screening

Favorable Safety Profile Through 36 Months

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, today announced that its *iDose*® TR sustained-release travoprost implant continued to provide sustained substantial reductions in intraocular pressure (IOP) in a 36-month analysis of the 36-month Phase 2b clinical trial conducted under a U.S. Investigational New Drug (IND) protocol.

Administered during a micro-invasive procedure, the *iDose TR* contains a novel formulation of travoprost, a prostaglandin analog used to reduce IOP, and was designed to continuously release therapeutic levels of the medication for at least one year. Once all travoprost is released, the *iDose TR* was designed to be removed and replaced with a new *iDose TR*, thus potentially offering an alternative to daily eye drop treatment.

The 154-subject, multi-center, randomized, double-blind Phase 2b trial was designed to evaluate a single administration of one of two *iDose TR* models with different travoprost release rates compared to topical timolol ophthalmic solution, 0.5% BID (twice a day). The primary efficacy endpoint agreed on with the U.S. Food and Drug Administration (FDA) is the non-inferiority comparison to timolol over the first three months after a single implantation of *iDose TR*. The currently reported Phase 2b results are based on an analysis conducted at 36 months for all 154 subjects randomized into the trial, with 51, 54 and 49 subjects randomized to *iDose TR* fast-release arm, *iDose TR* slow-release arm and timolol active comparator arm, respectively. The subjects randomized to either *iDose TR* arm received a single intracameral implant while the subjects randomized to the timolol active comparator received twice-daily eye drops over the 36-month evaluation period, which equates to approximately 2,190 eye drops per eye, per protocol.

Topline summary results and observations from the analysis of the *iDose TR* Phase 2b clinical trial at 36 months are as follows:

- 70% and 68% of subjects in the fast- and slow-release *iDose TR* arms, respectively, were well-controlled with the same or fewer IOP-lowering topical medications at 36 months versus screening, versus 46% of subjects in the timolol control arm.
- In this responder group, average IOP reductions from baseline observed at 36 months were 8.3 mmHg and 8.5 mmHg in the fast- and slow-release *iDose TR* arms, respectively, versus 8.2 mmHg in the timolol control arm.
- Overall, *iDose TR* subjects performed similarly to timolol subjects at 36 months in terms of mean IOP reductions with fewer topical medications versus timolol.
- The 36-month Phase 2 data also continued to demonstrate a favorable safety profile for *iDose TR*, with no clinically significant corneal endothelial cell loss, no serious corneal adverse events and no adverse events of periorbital fat atrophy and conjunctival hyperemia reported to date in either elution arm.

“These latest Phase 2 results further underscore the potential of *iDose TR* to safely provide multiple years of sustained dropless therapy and help tackle the significant problem of patient non-adherence to and chronic side effects associated with topical glaucoma medication regimens,” said Thomas Burns, Glaukos president and chief executive officer. “We believe there is an important unmet clinical need and strong appetite within the ophthalmic community for safe, effective and durable dropless pharmaceutical alternatives to traditional topical medications. These data reaffirm our excitement about the potential commercial prospects of *iDoseTR* and mark another critical step forward in the advancement of our novel and comprehensive product pipeline designed to transform the treatment of chronic eye diseases for the benefit of patients worldwide.”

On June 10, 2021, Glaukos announced the completion of patient enrollment and randomization in its ongoing Phase 3 clinical program for *iDose TR*. The Phase 3 program consists of two prospective, randomized, double-masked clinical trials designed to compare the safety and efficacy of *iDose TR* to topical timolol ophthalmic solution, 0.5%, in reducing elevated intraocular pressure in subjects with open-angle glaucoma (OAG) or ocular hypertension. The primary efficacy endpoint of the Phase 3 studies is non-inferiority comparison to topical timolol 0.5% BID over the first 3 months, and safety evaluations for up to 12 months. The Phase 3 trials randomized a total of 1,150 subjects across 89 clinical sites, the majority of which are in the United States. The 12-month *iDose TR* Phase 3 trial results are expected to support Glaukos’ targeted NDA submission in 2022 and FDA approval for *iDose TR* in 2023.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. 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 2012, its next-generation *iStent inject*[®] device in the United States in 2018, and most recently, the *iStent inject W* device in 2020. In corneal health, Glaukos’ proprietary suite of single-use, bio-activated pharmaceuticals are designed to strengthen, stabilize and reshape the cornea through a process called corneal collagen cross-linking to treat corneal ectatic disorders and correct refractive conditions. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

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 timing and extent to which we submit our U.S. NDA submission for iDose TR, obtain regulatory approval for iDose TR or other investigational products, our ability to successfully commercialize such products, the ability to obtain and maintain adequate financial coverage and reimbursement for our products, and the continued efficacy and safety profile of our products. These and other risks, uncertainties and factors related to Glaukos, and our business are described in detail under the caption "Risk Factors" and elsewhere in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which was filed with the Securities and Exchange Commission (SEC) on November 8, 2021. 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.

Media Contact:
Cassandra Dump
(619) 971-1887
Cassy@pascalecommunications.com

Investor Contact:
Chris Lewis
Sr. Director, Investor Relations & Corporate Strategy & Development
(949) 481-0510
clewis@glaukos.com

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