Glaukos’ iDose® TR Demonstrates Sustained IOP Reduction and Favorable Safety Profile Over 24 Months in Phase 2b Study

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24-Month Average IOP Reductions of 7.9 mmHg and 7.4 mmHg in Fast- and Slow-Release iDose TR Arms, Respectively

Favorable Safety Profile Through 24 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 24-month interim analysis of the ongoing 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 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 interim analysis conducted at 24 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. All IOP analyses were calculated using all IOP observations over 24 months weighted equally with no imputations for protocol-mandated medications. The subjects randomized to either *iDoseTR* arm received a single intracameral implant while the subjects randomized to the timolol active comparator received twice-daily eye drops over the 24-month evaluation period, which equates to approximately 1,460 eye drops per eye, per protocol.

Topline summary results and observations from the interim analysis of the *iDose TR* Phase 2b clinical trial at 24 months are as follows:

- Average IOP reductions from baseline observed during the first 24 months were 7.9 mmHg and 7.4 mmHg in the fast- and slow-release *iDose TR* arms, respectively, versus 7.8 mmHg in the timolol control arm.
- Average IOP reductions from baseline observed during the first 24 months were 29% and 28% in the fast- and slow-release *iDose TR* arms, respectively, versus 30% in the timolol control arm.
- Over the first 24 months, 23% and 20% of subjects in the fast- and slow-release *iDose TR* arms reported average IOP reductions from baseline of at least 40%, respectively, versus 13% in the timolol control arm.
- Subjects who had been on a single pre-study IOP-lowering medication at the screening visit had greater average IOP reduction over 24 months on *iDose TR* versus the pre-study IOP-lowering eye drops.
- The *iDoseTR* arms progressed at a similar number of protocol-mandated medications compared to the timolol control arm, with all arms requiring an average of less than one medication added through two years.
- The 24-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 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 glaucoma pharmaceutical therapy and tackle the significant problem of patient non-adherence to 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 sustained-release pharmaceutical alternatives to traditional topical medications. These data reaffirm our excitement about the potential commercial prospects of *iDoseTR*. Our near-term focus remains on completing enrollment in our ongoing *iDose TR* Phase 3 clinical program, which will mark another critical step forward in the advancement of our novel and comprehensive product pipeline designed to transform glaucoma therapy.”

Glaukos continues to progress towards enrollment completion in its ongoing Phase 3 clinical program for *iDose TR* despite the ongoing impact of the COVID-19 pandemic on enrollment. 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 are expected to randomize a total of approximately 1,100 subjects across approximately 100 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’ NDA submission in 2022 and the company is now targeting FDA approval for *iDose TR* in 2023.

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS), which involves insertion of a micro-scale device from within the eye's anterior chamber through a small corneal incision. Glaukos’ MIGS devices are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor. Glaukos received U.S. Food and Drug Administration (FDA) approval for its first-generation MIGS device, the *iStent*®, in 2012. Its second-generation *iStent inject*®, which received FDA approval in 2018, and its latest *iStent inject W* device, which received FDA approval in 2020, include two stents preloaded in an auto-injection mechanism that facilitates stent insertion into multiple trabecular meshwork locations through a single corneal incision. The *iStent inject* is also approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Japan, Singapore and other international markets. Glaukos is pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy pipeline products, all of which are investigational in the United States.

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 July 2012, its next-generation *iStent inject* device in the United States in September 2018, and most recently, the *iStent inject W* device in October 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 continued efficacy and safety profile of our products, the extent to which we may obtain regulatory approval for the *iDose* or other investigational products, and our ability to successfully commercialize such 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, 2020 filed with the Securities and Exchange Commission on November 5, 2020. 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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