Glaukos Announces Positive Topline Outcomes for Both Phase 3 Pivotal Trials of iDose TR, Achieving Primary Efficacy Endpoints and Demonstrating Favorable Tolerability and Safety Profiles

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Phase 3 Pivotal Trials Met Pre-Specified Primary Efficacy Endpoints for Both Doses of iDose TR (Fast- and Slow-Release Models), Supporting Anticipated Upcoming NDA Submission

93% of Slow-Release iDose TR Subjects Remained Well-Controlled on the Same or Fewer IOP-Lowering Topical Medications at 12 Months After a Single Administration of iDose TR, Including 81% Completely Free of IOP-Lowering Medications

iDose TR Demonstrated Excellent Tolerability and a Favorable Safety Profile Through 12 Months

ALISO VIEJO, 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 positive topline data for both Phase 3 pivotal trials of *iDose TR* that successfully achieved its pre-specified primary efficacy endpoints through 3 months in both Phase 3 trials and demonstrated excellent tolerability and a favorable safety profile through 12 months.

Topline summary results and observations from the *iDose TR* Phase 3 pivotal trials are as follows:

- For each of the two Phase 3 *iDose TR* pivotal trials, GC-010 and GC-012, both the fast- and slow-release *iDose TR* arms achieved the pre-specified primary efficacy endpoint of non-inferiority to the active comparator arm (twice-daily topical timolol ophthalmic solution, 0.5%) through 3 months.
- For the GC-010 trial, the intraocular pressure (IOP) reductions from baseline over the first 3 months were 6.6-8.5 mmHg in the slow-release *iDose TR* arm, versus 6.6-7.7 mmHg in the timolol control arm (mmHg range represents IOP reduction means across the six U.S. Food and Drug Administration (FDA) pre-specified timepoints of 8 a.m. and 10 a.m. at Day 10, Week 6 and Month 3). For the GC-012 trial, IOP reductions from baseline over the first 3 months were 6.7-8.4 mmHg in slow-release *iDose TR* arm, versus 6.8-7.2 mmHg in the timolol control arm.
- 93% of slow-release *iDose TR* subjects remained well-controlled on the same or fewer IOP-lowering topical medications at 12 months compared to screening after a single administration of *iDose TR,* versus 67% of timolol control subjects in both Phase 3 trials. Additionally, 81% of slow-

release *iDose TR* subjects were completely free of IOP-lowering topical medications at 12 months across both trials.
- *iDose TR* demonstrated excellent tolerability with 98% of slow-release *iDose TR* subjects continuing in the trial at 12 months, versus 95% of timolol control subjects across both Phase 3 trials.
- *iDose TR* demonstrated a favorable safety profile through 12 months, with no adverse events of corneal endothelial cell loss, no serious corneal adverse events and no adverse events of periorbital fat atrophy. Notably, conjunctival hyperemia occurred at a very low rate of 3% for slow-release *iDose TR* subjects. The most frequent adverse event for slow-release *iDose TR* subjects was mild transient iritis at a rate of 6% in both Phase 3 trials.
- In-office administration of *iDose TR* was successfully employed with various subjects across multiple sites with outcomes that were consistent with the Phase 3 trials, thus demonstrating the feasibility of *iDose TR* administration in the office setting.

“We are very pleased to announce these robust and replicative positive Phase 3 pivotal data results for *iDose TR*, which mark a major milestone for our company and powerfully reaffirms our view that *iDose TR* can be a transformative novel technology able to fundamentally improve the glaucoma treatment paradigm for patients,” said Thomas Burns, Glaukos chairman and chief executive officer. “We believe there is an important unmet clinical need and strong appetite within the ophthalmic community for safe, effective and sustained dropless pharmaceutical alternatives to traditional topical medications. These data leave us ideally positioned for an upcoming NDA submission and FDA review for *iDose TR* as we continue to advance our mission to transform vision for the benefit of patients around the globe suffering from chronic eye diseases.”

Based on the combined efficacy and safety results from both Phase 3 pivotal trials, Glaukos plans to move forward with its plans for an NDA submission to the U.S. FDA for the slow-release *iDose TR* model, with an expected FDA review and decision completed by the end of 2023.

Administered during a micro-invasive procedure, the *iDose TR* contains a novel formulation of travoprost, a prostaglandin analog used to reduce IOP. 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 *iDose TR* Phase 3 clinical program consists of two prospective, randomized, double-masked pivotal clinical trials designed to compare the safety and efficacy of a single administration of one of two *iDose TR* models with different travoprost release rates (referred to as the fast- and slow-release *iDose TR* models, respectively) to topical timolol ophthalmic solution, 0.5% BID (twice a day), in reducing elevated IOP in subjects with open-angle glaucoma (OAG) or ocular hypertension. The two *iDose TR* pivotal trials are nearly identical in terms of design, protocol, predefined endpoints, size and randomization.

The first of the two Phase 3 pivotal trials, referred to as GC-010, randomized a total of 590 subjects, comprised of 200 subjects in the slow-release *iDose TR* arm, 197 subjects in the fast-release *iDose TR* arm and 193 subjects in the timolol active comparator arm. The second of the two Phase 3 pivotal trials, referred to as GC-012, randomized a total of 560 subjects, comprised of 183 subjects in the slow-release *iDose TR* arm, 185 subjects in the fast-release *iDose TR* arm and 193 subjects in the timolol active comparator arm. In total, the Phase 3 trials randomized a total of 1,150 subjects across 89 clinical sites.

The primary efficacy endpoint of the Phase 3 studies was a non-inferiority comparison to topical timolol 0.5% BID over the first 3 months, defined as time-matched diurnal IOP measurements at 8 a.m. and 10 a.m. at Day 10, Week 6 and Month 3. Primary safety evaluations were performed through 12 months.

Mean baseline IOP was approximately 24 mmHg across each arm in each study. Approximately 81% of slow-release *iDose TR* subjects had OAG while the remaining 19% had ocular hypertension. Approximately 67% of slow-release *iDose TR* subjects were on one or more IOP-lowering medications at screening, including 23% of subjects who were on two or more IOP-lowering medications at screening.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on developing and commercializing novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. Glaukos first developed Micro-Invasive Glaucoma Surgery (MIGS) as an alternative to the traditional glaucoma treatment paradigm, launching its first MIGS device commercially in 2012, and continues to develop a portfolio of technologically distinct and leverageable platforms to support ongoing pharmaceutical and medical device innovations. Products or product candidates for each of these platforms are designed to advance the standard of care through better treatment options across the areas of glaucoma, corneal disorders and retinal diseases.

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 obtain regulatory approval for investigational products such as iDose TR, our ability to successfully commercialize such products, the ability to obtain and maintain adequate financial coverage and reimbursement for this product, and the continued efficacy and safety profile of this product as reported in the pivotal trials. 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 June 30, 2022, which was filed with the Securities and Exchange Commission (SEC) on August 5, 2022. Our filings with the SEC 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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