Glaukos Achieves Pipeline Milestone with Completion of Patient Enrollment in U.S. NDA Phase 3 Clinical Trials for iDose® TR

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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 the completion of patient enrollment and randomization in its U.S. Food and Drug Administration (FDA) New Drug Application (NDA) Phase 3 clinical trials for the *iDose® TR* sustained-release travoprost implant.

The *iDose TR* Phase 3 clinical program consists of two prospective, randomized, double-masked 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 to topical timolol ophthalmic solution, 0.5% BID (twice a day), in reducing elevated intraocular pressure (IOP) 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.

"We are excited to announce this important milestone for *iDose TR*, marking a critical step in bringing this promising technology one step closer to being able to safely provide 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 appreciate the commitment and dedication of the clinical investigators, who play a vital role in bringing new innovations to patients suffering with glaucoma disease. We look forward to following these patients' outcomes as we target U.S. NDA submission in 2022 and FDA approval in 2023."

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.

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, obtain regulatory approval for the iDose TR or other investigational products, our ability to successfully commercialize such products, and the continued efficacy and safety profile of our products when commercially marketed as compared to their pre-approval clinical trial results. 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 March 31, 2021, which was filed with the Securities and Exchange Commission (SEC) on May 6, 2021, and our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 1, 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.

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