Glaukos Announces Completion of Patient Enrollment in 510(k) Pivotal Study for PRESERFLO™ MicroShunt

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ALISO VIEJO, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic pharmaceutical and medical technology company focused on novel therapies for the treatment of glaucoma, corneal disorders, and retinal diseases, today announced the completion of patient enrollment in its U.S. 510(k) pivotal study evaluating the *PRESERFLO™ MicroShunt* in adult patients with primary open-angle glaucoma (POAG) who failed previous medical and surgical treatment.

The *PRESERFLO MicroShunt* is a novel, ab-externo glaucoma drainage device designed to lower intraocular pressure (IOP). Constructed from a proprietary, biocompatible material known as SIBS [poly(styrene-block-isobutylene-block-styrene)], the *PRESERFLO MicroShunt* is an 8.5 mm flexible drainage device featuring planar fins designed to facilitate tissue fixation through a minimally-invasive procedure while helping maintain device positioning and minimize leakage.

“The completion of patient enrollment in our U.S. pivotal study represents an important milestone toward potentially bringing the *PRESERFLO MicroShunt* to U.S. patients with advanced glaucoma who are at risk for significant vision loss,” said Thomas Burns, Glaukos chairman and chief executive officer. “We believe the *PRESERFLO MicroShunt* has the potential to address an important unmet clinical need by providing glaucoma specialists with an elegant, ab-externo surgical alternative to conventional filtration procedures such as trabeculectomy and tube shunt surgery. As we advance into the next phase of this clinical program through patient follow-up, we remain committed to expanding our comprehensive, best-in-class portfolio of novel glaucoma therapies designed to address the evolving needs of patients and physicians across the full continuum of glaucoma care.”

The *PRESERFLO MicroShunt* prospective, multi-center, single-arm clinical trial enrolled patients who had previously undergone unsuccessful incisional or cilioablative glaucoma surgery and whose IOP remained inadequately controlled with IOP-lowering medications. The study successfully enrolled its target of at least 110 patients across clinical sites in the United States and Canada. The study’s primary effectiveness endpoint is a 20% or greater reduction in mean diurnal IOP from baseline at 12 months postoperatively without an increase in the number of IOP-lowering medication classes from baseline. Glaukos intends to use the study results to support a future FDA marketing submission for the *PRESERFLO MicroShunt*.

Glaukos holds the exclusive rights to develop and commercialize the *PRESERFLO MicroShunt* in the United States, Australia, New Zealand, Canada, Brazil, and Mexico under its license agreement with Santen Pharmaceutical Co., Ltd. The device is currently approved and commercialized in several of

these markets, including Canada and Australia, where surgeon adoption continues to grow alongside an expanding body of favorable real-world evidence supporting the device's safety and effectiveness.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic pharmaceutical and medical technology 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. In 2024, Glaukos commenced commercial launch activities for *iDose*® *TR*, a first-of-its-kind, long-duration, intracameral procedural pharmaceutical designed to deliver 24/7 glaucoma drug therapy inside the eye for extended periods of time. Glaukos also markets the only FDA-approved corneal cross-linking therapy utilizing a proprietary bio-activated pharmaceutical for the treatment of keratoconus, a rare corneal disorder. Glaukos continues to successfully develop and advance a robust pipeline of novel, dropless platform technologies designed to meaningfully advance the standard of care and improve outcomes for patients suffering from chronic eye 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 the *PRESERFLO MicroShunt*, 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 Annual Report on Form 10-K for the year ended December 31, 2025, which was filed with the SEC on February 23, 2026, along with Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, which was filed with the SEC on April 30, 2026. 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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