Glaukos Announces FDA 510(k) Clearance of iStent infinite®

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MIGS Founder Leads with the First-Ever Micro-Invasive Implantable Device for Standalone Glaucoma Treatment

Novel Three-Stent Injectable System Designed to Provide Foundational, 24/7 IOP Control

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 that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the *iStent infinite*® Trabecular Micro-Bypass System indicated for use in a standalone procedure to reduce elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma uncontrolled by prior medical and surgical therapy.

The *iStent infinite* includes three heparin-coated titanium stents preloaded into an auto-injection system that allows the surgeon to inject stents across a span of up to approximately six clock hours around Schlemm's canal, the eye's primary drainage channel. Once in place, the stents are designed to lower IOP by restoring the natural, physiological outflow of aqueous humor. The *iStent infinite* has a similar mechanism of action to the company's two-stent *iStent inject*® *W Trabecular Micro-Bypass System*, which is approved by the FDA for the reduction of IOP in adult mild-to-moderate primary open-angle glaucoma patients undergoing concomitant cataract surgery.

"This FDA clearance for *iStent infinite* represents a significant milestone for Glaukos and the MIGS market as the first FDA-cleared micro-invasive implantable device indicated for use as a standalone treatment option for glaucoma patients not undergoing concomitant cataract surgery," said Thomas Burns, chairman and chief executive officer. "Supported by strong pivotal data highlighting favorable safety and effectiveness, we believe *iStent infinite* provides ophthalmic surgeons a compelling new interventional glaucoma alternative designed to provide foundational, 24/7 IOP control for their patients in need. We are grateful to the clinical investigators and patients who participated in the clinical trial for their instrumental roles in helping us reach this pioneering achievement and bring *iStent infinite* to the U.S."

The company intends to commence initial commercial launch activities for *iStent infinite* later this year.

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 has since developed 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, 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 March 31, 2022, which was filed with the Securities and Exchange Commission (SEC) on May 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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