Glaukos Announces Submission of Supplemental Pre-Market Approval Application for iStent infinite™

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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 that it has submitted a supplemental pre-market approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the *iStent infinite™Trabecular Micro-Bypass System*.

The *iStent infinite* is an investigational devicedesigned for use in a standalone procedure to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma uncontrolled by prior surgical or medical therapy. It 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* is similar 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 filing marks a significant achievement for Glaukos as we continue to advance our deep pipeline of novel glaucoma surgical devices and sustained pharmaceuticals," said Thomas Burns, president and chief executive officer. "Supported by strong pivotal data highlighting favorable safety and effectiveness, we believe *iStent infinite* may provide ophthalmic surgeons with a compelling new treatment alternative in a standalone procedure for patients with open-angle glaucoma uncontrolled by prior surgical or medical therapy."

The *iStent infinite* prospective, unmasked, multi-center, single-arm clinical trial enrolled subjects who had undergone prior unsuccessful incisional or cilioablative glaucoma surgery and had IOP not adequately controlled with IOP-lowering medications as well as subjects who had not undergone prior incisional or cilioablative glaucoma surgery but were on maximally tolerated IOP-lowering medications with uncontrolled IOP. In the trial, 72 subjects were implanted with the *iStent infinite* at 15 separate clinical sites.

Patients entered the *iStent infinite* IDE pivotal study with a mean baseline IOP of 23.4 mmHg on an average of 3.1 medications and an average of 2 failed prior surgeries. At 12 months, 76% of subjects achieved 20% or greater reduction in mean diurnal IOP from baseline on the same or lower ocular hypotensive medication burden. Further, more than 50% of subjects achieved Month 12 IOP reduction ≥ 30%. Subjects also achieved a 13% reduction in mean medication burden at 12 months. The safety

profile in the study was highly favorable, with no explants, infections or device-related interventions or hypotony reported through 12 months.

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 *iStent infinite* 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 June 30, 2021 filed with the Securities and Exchange Commission on August 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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