



U.S. IDE Trial Results for Glaukos' iStent infinite™ Show Substantial Reduction in IOP

2021-01-13

Substantial IOP Reduction Observed with Highly Favorable Safety Profile Through 12 Months

76% of Subjects Achieved 20% or Greater Reduction in Month 12 IOP with Same or Lower Medication Burden

Data Suggest iStent infinite May Offer Ophthalmic Surgeons a Compelling New Treatment Option in Standalone Procedure for Managing Glaucoma Patients' IOP and Disease Progression

FDA Approval Targeted for Late 2021

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 12-month U.S. Investigational Device Exemption (IDE) pivotal trial data showed that its *iStent infinite™ Trabecular Micro-Bypass System* achieved a substantial reduction in mean diurnal intraocular pressure (IOP) in 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. All surgeons performing the *iStent infinite* procedures were board-certified glaucoma specialists.

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 $\geq 30\%$. Subjects also achieved a 13% mean reduction in 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.

"We are excited to announce this strong pivotal data highlighting the favorable safety and effectiveness of the *iStent infinite*. These data further underscore our view that *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,” 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 from glaucoma and at risk for significant vision loss. We look forward to working cooperatively with the FDA as we prepare for an upcoming regulatory submission and continue to target U.S. approval of the *iStent infinite* in late 2021.”

The *iStent infinite* is an investigational device designed for use in a standalone procedure to reduce elevated intraocular pressure 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 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.

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS), which involves insertion of a micro-scale device from within the eye’s anterior chamber through a small corneal incision. Glaukos’ MIGS devices are designed to reduce IOP by restoring the natural outflow pathways for aqueous humor. Glaukos received U.S. Food and Drug Administration (FDA) approval for its first-generation MIGS device, the *iStent*[®], in 2012. Its second-generation *iStent inject*, which received FDA approval in 2018, and its latest *iStent inject W* device, which received FDA approval in 2020, include two stents preloaded in an auto-injection mechanism that facilitates stent insertion into multiple trabecular meshwork locations through a single corneal incision. The *iStent inject* is also approved in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Japan, Singapore and other international markets. Glaukos is pursuing FDA approval for additional MIGS surgical and sustained pharmaceutical therapy pipeline products, all of which are investigational in the United States.

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 September 30, 2020 filed with the Securities and Exchange Commission on November 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.

View source version

on businesswire.com: <https://www.businesswire.com/news/home/20210113005168/en/>

Media Contact:

Cassandra Dump

(619) 971-1887

Cassy@pascalecommunications.com

Investor Contact:

Chris Lewis

Director, Investor Relations & Corporate Strategy & Development

(949) 481-0510

clewis@glaukos.com

Source: Glaukos Corporation