Health Canada Approves the Glaukos iStent inject®

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New Micro-Scale Glaucoma Device May Be Used as a Standalone Procedure or in Combination with Cataract Surgery

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, today announced that Health Canada has approved its *iStent inject*® *Trabecular Micro-Bypass Stent* for the reduction of intraocular pressure (IOP) in patients diagnosed with primary open-angle glaucoma, pseudoexfoliative glaucoma or pigmentary glaucoma.

With this approval, the *iStent inject* can be used in combination with cataract surgery in patients who require IOP reduction and/or would benefit from glaucoma medication reduction. *iStent inject* is also indicated as a standalone procedure for patients who continue to have elevated IOP despite prior treatment with glaucoma medications or conventional glaucoma surgery.

The *iStent inject* relies on a similar fluidic method of action as the company's flagship *iStent*® *Trabecular Micro-Bypass Stent*, which was approved by Health Canada for use in combination with cataract surgery in 2009. The *iStent inject* system includes an injector that delivers two preloaded stents, providing an ophthalmic surgeon the ability to target the placement of the stents through a single corneal entry point for greater IOP reduction. Made from surgical-grade non-ferromagnetic titanium that is coated with heparin, each *iStent inject* stent is approximately 0.3 mm in diameter and 0.4 mm long, or roughly one-third the size of the original *iStent.*

Glaukos pioneered Micro-Invasive Glaucoma Surgery (MIGS) to address the shortcomings of conventional glaucoma treatment options, which include chronic use of daily prescription eye drops or invasive surgeries. MIGS procedures involve insertion of a micro-scale device from within the eye's anterior chamber to restore the natural outflow pathways for aqueous humor and provide sustained IOP reduction.

"The Health Canada approval of the *iStent inject* is another important advancement in the MIGS category," said Ike K. Ahmed, MD, FRCSC, Trillium Health Partners and University of Toronto. "MIGS devices, used early in the glaucoma treatment algorithm, can provide an effective alternative to additional topical medications that can create adherence challenges, side effects and quality-of-life issues. The availability of *iStent inject* with expanded indications for use as a standalone procedure or in conjunction with cataract surgery means more patients can now benefit from this exciting new class of glaucoma interventions."

As part of the approval process, Health Canada reviewed results of two investigational and three post-market studies. These five studies included 57 investigators in nine countries who implanted a total of 346 subjects with *iStent inject.* In one trial evaluating *iStent inject* as a standalone treatment, 66% of *iStent inject* subjects (n=58 of 88) achieved the primary endpoint of IOP = 18 mmHg at 12 months without medications. The secondary endpoint, IOP = 18 mm Hg at 12 months regardless of medications, was achieved by 81% of *iStent inject* subjects (n=71 of 88). Furthermore, 72% of *iStent inject* subjects (n=63 of 88) experienced a = 20% IOP reduction without medications at 12 months.

The *Glaucoma Research Society of Canada* estimates that glaucoma affects more than 400,000 Canadians. Glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. Open-angle glaucoma is the most common form of the disease. There is no cure for the glaucoma and reducing IOP is the only proven treatment.

“We are committed to remaining at the forefront of glaucoma innovation and are building a comprehensive portfolio of micro-scale injectable therapies that can serve the full spectrum of surgeon and patient needs,” said Thomas Burns, president and CEO of Glaukos. “This approval marks an important step forward in our strategy to extend the reach of our *iStent* technology platform in key regions around the world.”

The *iStent inject* is already approved in the European Union and Australia. Glaukos is pursuing regulatory approval in additional markets, including the United States where the company is conducting IDE clinical trials to evaluate two versions of the *iStent inject,* one in combination with cataract surgery and another as a standalone procedure in phakic and pseudophakic glaucoma patients.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures to transform the treatment of glaucoma, one of the world’s leading causes of blindness. 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 and is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale injectable therapies designed to address the complete range of glaucoma disease states and progression. The company believes the *iStent,* measuring 1.0 mm long and 0.33 mm wide, is the smallest medical device ever approved by the FDA.

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. These include statements about our plans, objectives, strategies and prospects regarding, among other things, our *iStent and iStent inject*® products, efforts to secure regulatory approvals, and U.S. and international commercialization efforts. 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. Therefore, they may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this presentation. 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 these forward-

looking statements, 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. The known risks, uncertainties and factors are described in detail under the caption “Risk Factors” and elsewhere in our filings with the Securities and Exchange Commission (SEC) and available in the Investor section of our website at www.glaukos.com or at www.sec.gov.

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