Glaukos Announces Five-Year Extensions for Three Category III CPT Codes Related to Micro-Invasive Glaucoma Surgery

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AMA CPT® Editorial Panel Action Applies to Codes Describing Trabecular Meshwork and Suprachoroidal Stent Procedures

SAN CLEMENTE, 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 the Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association has granted five-year extensions to three Category III CPT codes that describe insertion of aqueous drainage devices into the anterior chamber of the eye using Micro-Invasive Glaucoma Surgery (MIGS).

CPT codes are used by physicians and other healthcare providers to report and receive Medicare reimbursement for healthcare services. In consultation with and with the support of the American Academy of Ophthalmology, American Glaucoma Society and American Society of Cataract and Refractive Surgery, Glaukos requested and received extensions through December 31, 2023 on the following Category III CPT codes:

- 0191T, which describes insertion of an initial anterior segment aqueous drainage device such as the company's *iStent® Trabecular Micro-Bypass Stent* and *iStent inject® Trabecular Micro-Bypass Stent* into the trabecular meshwork. The *iStent* was approved by the U.S. Food & Drug Administration (FDA) and launched in 2012. The *iStent inject* is currently being evaluated in U.S. clinical trials and has not been approved by the FDA.
- 0253T, which describes insertion of an anterior segment aqueous drainage device such as the company's *iStent SUPRA® Suprachoroidal Micro-Bypass Stent* into the suprachoroidal space. The *iStent SUPRA* is currently being evaluated in U.S. clinical trials and has not been approved by the FDA.
- 0376T, which is an add-on code that describes insertion of additional anterior segment aqueous drainage devices, as with the *iStent inject.*

"The AMA CPT Editorial Panel's decision to grant these extensions is important to the continued surgeon adoption of *iStent* and MIGS, a new technology class we pioneered to provide glaucoma patients a viable potential alternative to daily, multi-dose prescription eye drops or complex surgeries," said Thomas Burns, Glaukos president and chief executive officer. "As we pursue FDA approval of our next-generation *iStent* technologies, we are pleased to have the corresponding CPT codes already in

place and will use this time to continue to build upon the growing body of published research that documents their clinical performance."

The *iStent*, which is the industry's flagship MIGS device, is inserted through the trabecular meshwork and into Schlemm's canal via a small corneal incision made during cataract surgery. Once in place, it is designed to restore the natural, physiological outflow of aqueous fluid and reduce intraocular pressure (IOP). The company is also pursuing FDA approval of two versions of its next-generation *iStent inject* device: one for use in combination with cataract surgery and another for use in a standalone procedure. The *iStent inject* is designed to deploy two stents into separate trabecular meshwork locations and is being evaluated for IOP reduction. The company is also pursuing FDA approval of a third MIGS device, the *iStent SUPRA*, which accesses a secondary pathway for aqueous humor outflow.

Glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. There is no cure for the disease and reducing IOP is the only proven treatment. According to Market Scope, more than 80 million people worldwide have glaucoma, including 4.5 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.6 million people in the United States.

About *iStent Trabecular Micro-Bypass Stent*

Indication for Use: The *iStent Trabecular Micro-Bypass Stent* is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Contraindications: The *iStent* is contraindicated in eyes with primary or secondary angle closure glaucoma, including neovascular glaucoma, as well as in patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

Warnings: Gonioscopy should be performed prior to surgery to exclude PAS, rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. The *iStent* is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions, please see label for details.

Precautions: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the *iStent* has not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, chronic inflammation, or an abnormal anterior segment, in pseudophakic patients with glaucoma, in patients with pseudoexfoliative glaucoma, pigmentary, and uveitic glaucoma, in patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg after "washout" of medications, or in patients with prior glaucoma surgery of any type including argon laser trabeculoplasty, for implantation of more than a single stent, after complications during cataract surgery, and when implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract.

Adverse Events: The most common post-operative adverse events reported in the randomized pivotal trial included early post-operative corneal edema (8%), BCVA loss of ≥ 1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%), early post-operative anterior chamber cells (3%), and early post-operative corneal abrasion (3%). Please refer to Directions for Use for additional adverse event information.

Caution: Federal law restricts this device to sale by, or on the order of, a physician. Please reference the Directions for Use labeling for a complete list of contraindications, warnings, precautions, and adverse events.

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. 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 of our products and the extent to which we may obtain regulatory approval for any of the products discussed herein; the extent to which we may obtain reimbursement coverage from Medicare or commercial payers for procedures involving our technologies; and the extent to which the company will be able to achieve its goal of providing glaucoma surgeons and patients a comprehensive set of options to address a range of glaucoma disease states and progression. These risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for 2016, which was filed with the Securities and Exchange Commission on March 15, 2017. 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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