Glaukos iStent® Trabecular Micro-Bypass Stent Approved in Japan

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Approved by the MHLW for Use in Combination with Cataract Surgery, iStent Will Be First-Ever Ab Interno Micro-Scale Glaucoma Device Available in Japan

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 the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved its iStent® Trabecular Micro-Bypass Stent for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients diagnosed with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication. The iStent is the first-ever ab interno Micro-Invasive Glaucoma Surgery (MIGS) device approved for use in Japan. Glaukos pioneered MIGS to address the shortcomings of conventional glaucoma treatment options, which include chronic use of daily prescription eye drops or invasive surgeries.

Packaged in a pre-loaded configuration, the iStent is inserted through a small corneal incision made during cataract surgery and placed into Schlemm’s canal, a circular channel in the eye that collects aqueous humor and eventually delivers it into the bloodstream. If aqueous humor cannot drain appropriately through the trabecular meshwork and Schlemm’s canal, pressure within the eye (IOP) can become elevated. The iStent is designed to restore the natural outflow pathways for aqueous humor and provide sustained IOP reduction. Clinical studies have demonstrated that inserting the iStent in combination with cataract surgery yields an overall safety profile and recovery rate similar to cataract surgery alone. Cataract surgery has minimal complications and is the most commonly performed ophthalmic procedure today.
The iStent was approved by the U.S. Food and Drug Administration (FDA) in June 2012 and is currently approved for sale in 27 countries worldwide. Made of surgical-grade non-ferromagnetic titanium that is coated with heparin, the iStent is approximately 1.0 mm long and 0.33 mm wide. Glaukos believes it is the smallest device ever approved by either the FDA or MHLW.

“The iStent represents an important new option for effectively managing elevated IOP in glaucoma, a disease that is a leading cause of blindness worldwide,” said Thomas Burns, Glaukos president and chief executive officer. “We appreciate the efforts of the MHLW to evaluate and approve the iStent and we are eager to introduce this breakthrough MIGS technology to Japanese surgeons and patients. This achievement also marks an important milestone for Glaukos as we expand our presence in the Asia Pacific region.”

In anticipation of the iStent approval, Glaukos recently established a direct commercial team and formed a wholly owned subsidiary in Japan. The company expects to officially launch the iStent in Japan later this year once the iStent procedure is approved for reimbursement by MHLW.

According to Market Scope, glaucoma affects approximately 3 million people in Japan. Glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. Primary open-angle glaucoma is the most common form of the disease. There is no cure for glaucoma and reducing IOP is the only proven treatment.

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.

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 presentation. These potential risks and uncertainties include, without limitation, our dependence on the success and market acceptance of the iStent; our ability to obtain approval for reimbursement of the iStent procedure in Japan by MHLW; and our ability to successfully launch, market and sell the iStent in Japan. These and other 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, including our most recent Annual Report on Form 10-K for the year ended December 31, 2015, which we filed with the Securities and Exchange Commission on March 14, 2016. 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. 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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