FDA APPROVAL OF THE iSTENT TRABECULAR MICRO-BYPASS

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Laguna Hills, CA (June 25, 2012) — Glaukos Corporation (Glaukos) announced today it has received U.S. Food and Drug Administration (FDA) approval for the iStent® Trabecular Micro-Bypass – the first-ever ab interno glaucoma implant to be approved in the United States. The iStent® is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open- angle glaucoma currently treated with ocular hypotensive medication.

" Glaukos Corporation is pleased to be a leader in an emerging new procedural class called MIGS (Micro Invasive Glaucoma Surgery)", said Thomas W. Burns, President & CEO, Director of Glaukos. "Over the last decade, we have developed a complete portfolio of glaucoma stents to treat open-angle glaucoma and to contribute substantially to this new class of surgery. We believe that the iStent micro-bypass offers a compelling new treatment option for glaucoma specialists and comprehensive ophthalmologists to advance glaucoma patient care".

iStent is a 1mm implant, comprised of non-ferromagnetic titanium, that is the smallest medical device known to be implanted into the human body . The iStent device is PN: 400-0053-2012-US Rev 0 Release Date 06/25/2012 implanted in conjunction with cataract surgery and placed ab interno into Schlemm's canal using an inserter and intraoperative gonioscopy.

The primary cause of elevated eye pressure in patients with primary open-angle glaucoma is the abnormality and impermeability of the trabecular meshwork, which creates resistance to normal outflow of aqueous humor. The iStent is designed to create a bypass through the trabecular meshwork to Schlemm's canal to improve aqueous outflow through the natural, physiologic pathway.

The IDE pivotal study for iStent conducted by Glaukos was the first prospective, randomized US IDE trial for a glaucoma device. The pivotal trial, conducted at 27 sites, enrolled 239 subjects with mild to moderate open angle glaucoma and clinically significant cataract. Subjects were randomized 1:1 to either iStent in conjunction with cataract surgery, or cataract surgery alone. The results showed that 68% of subjects in the iStent treatment group (combined cataract and iStent® implantation) met the primary endpoint of IOP ≤ 21 mm Hg with no medications at 12 months, compared to only 50% of subjects in the cataract surgery only group. This treatment difference of 18% in favor of the iStent® group on the primary endpoint at 12 months was statistically (p = .004) and clinically significant. Similar results were obtained on the secondary endpoint of a ≥20% IOP reduction versus baseline at 12 months with 64% of the iStent group achieving this endpoint compared to 47% in the cataract only group.(p=.01).

Because iStent is implanted ab-interno, the procedure is conjunctival-sparing and blebless and preserves future therapeutic and surgical options for glaucoma patients. Glaukos has enrolled over 4,000 patients worldwide in clinical studies evaluating iStent devices in open angle glaucoma.

" The iStent implant is a safe and compelling new treatment option to significantly reduce IOP in OAG patients undergoing cataract surgery," according to L. Jay Katz, MD, FACS., director of the Glaucoma Service at the Wills Eye Institute. "I am greatly encouraged by the introduction of this new MIGS procedural implant class and FDA approval of this innovative device".

Selected Important Safety Information about iStent Indication for Use

The iStent® Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) 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 nor 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 Corporation

Glaukos Corporation is a privately-held, venture capital funded ophthalmic company located in Laguna Hills, California. Glaukos® is a leader in the emerging MIGS procedural implant class and has pioneered and developed a complete portfolio and pipeline of micro-bypass devices for the treatment of open-angle glaucoma.

The Wall Street Journal recently named Glaukos to The Next Big Thing list, which identified and ranked venture-backed companies across all industries that have the capital, executive experience and investor know-how to succeed. Glaukos was selected from a pool of more than 5,000 companies and ranked 19 based on proprietary data from Dow Jones VentureSource and input from Dow JonesVentureWire's reporters and editors.