Glaukos Announces EU MDR Certification for iStent infinite® and Other Leading MIGS Therapies

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Regulatory Clearances Support Glaukos' Plans to Advance and Accelerate its Interventional Glaucoma Initiatives Globally

Marks the Company's First Regulatory Clearances Under the New EU Regulatory Framework

ALISO VIEJO, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic pharmaceutical and medical technology company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, today announced it has received European Union (EU) Medical Device Regulation (MDR) certification for *iStent infinite*®, along with several of its other leading micro-invasive glaucoma surgery (MIGS) technologies, including *iStent inject*® *W*. Glaukos' *iStent*® trabecular micro-bypass stenting platform primarily involves the insertion of a micro-scale surgical devices designed to reduce intraocular pressure by restoring the natural aqueous humor outflow pathways for patients suffering from glaucoma.

"We are pleased to receive these important regulatory clearances for our leading trabecular micro-bypass stenting devices, marking our company's first approvals under the new EU regulatory framework," said Thomas Burns, Glaukos chairman and chief executive officer. "These important milestones will not only help us maintain and grow our presence in Europe but also advance and accelerate our broader Interventional Glaucoma initiatives globally. We are eager to commence commercial launch activities for these novel MIGS therapies over the coming months."

These certifications affirm that *iStent infinite* and *iStent inject W* meet the stringent requirements of the EU MDR – a new, robust framework established to ensure high standards of quality, safety and effectiveness for medical devices marketed in the EU.

Glaukos is proud to be the corporate pioneer and global market leader in MIGS, with its family of *iStent* technologies supported by nearly 400 peer-reviewed publications, 20 plus years of clinical and commercial experience and more than one million *iStent* devices implanted worldwide since its inception. The company believes it offers the industry's most comprehensive offering of minimally-invasive, tissue-sparing glaucoma solutions, supporting its goal to provide a full range of options to fit surgeons' individual glaucoma treatment algorithms that offer the most favorable short- and long-term benefit-to-risk calculus at every stage of disease progression, from ocular hypertension through refractory disease, and in both combo-cataract and standalone procedures.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic pharmaceutical and medical technology company focused on developing and commercializing novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. Glaukos first developed Micro-Invasive Glaucoma Surgery (MIGS) as an alternative to the traditional glaucoma treatment paradigm, launching its first MIGS device commercially in 2012. In 2024, Glaukos commenced commercial launch activities for *iDose® TR*, a first-of-its-kind, long-duration, intracameral procedural pharmaceutical designed to deliver 24/7 glaucoma drug therapy inside the eye for extended periods of time. Glaukos also markets the only FDA-approved corneal cross-linking therapy utilizing a proprietary bio-activated pharmaceutical for the treatment of keratoconus, a rarely diagnosed corneal disorder. Glaukos continues to successfully develop and advance a robust pipeline of novel, dropless platform technologies designed to meaningfully advance the standard of care and improve outcomes for patients suffering from chronic eye diseases.

About *iStent infinite® Trabecular Micro-Bypass System (U.S.)*

Indication for Use: The iStent infinite Trabecular Micro-Bypass System Model iS3 is an implantable device intended to reduce the intraocular pressure (IOP) of the eye. It is indicated for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed.

Contraindications: The iStent infinite is contraindicated in eyes with angle-closure glaucoma where the angle has not been surgically opened, acute traumatic, malignant, active uveitic, or active neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or 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 congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization that could lead to improper placement of the stent and pose a hazard.

MRI Information: The iStent infinite is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details.

Precautions**:** The surgeon should monitor the patient postoperatively for proper maintenance of IOP. Three out of 61 participants (4.9%) in the pivotal clinical trial were phakic. Therefore, there is insufficient evidence to determine whether the clinical performance of the device may be different in those who are phakic versus in those who are pseudophakic.

Adverse Events: The most common postoperative adverse events reported in the iStent infinite pivotal trial included IOP increase ≥ 10 mmHg vs. baseline IOP (8.2%), loss of BSCVA ≥ 2 lines (11.5%), ocular surface disease (11.5%), perioperative inflammation (6.6%) and visual field loss ≥ 2.5 dB (6.6%).

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

For more information, visit www.glaukos.com.

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