Glaukos Announces US FDA Approval of NDA Supplement Allowing for Re-Administration of iDose® TR

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ALISO VIEJO, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic pharmaceutical and medical technology focused on novel therapies for the treatment of glaucoma, corneal disorders, and retinal diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved an NDA labeling supplement allowing for re-administration of *iDose® TR* using a repeat treatment protocol. The FDA approval is in response to Glaukos' 2025 NDA labeling supplement application, and reflects accumulated clinical evidence supporting the safety and tolerability of repeat use for *iDose TR*.

"We are pleased to announce this important labeling enhancement for *iDose TR*, which should help expand access for patients who may benefit from repeat treatment and provide physicians with greater flexibility in managing their glaucoma patients over time," said Thomas Burns, Glaukos chairman and chief executive officer. "This approval further validates *iDose TR's* established and proven safety profile and reinforces its leading position in addressing the strong and growing demand within the ophthalmic community for safe, effective, and sustained procedural pharmaceutical alternatives to traditional topical medications."

Under the updated labeling, physicians may now re-administer *iDose TR* more than once in patients who maintain a healthy cornea, as defined by corneal endothelial cell density parameters. In clinical studies, *iDose TR* has demonstrated a favorable long-term corneal safety profile, with no clinically significant corneal endothelial cell loss observed through three years across both the Phase 3 and Phase 2b studies. Additionally, results from the *iDose TR* exchange trial demonstrated a second administration of *iDose TR* and removal of the original *iDose TR* implant was safe and well-tolerated, with the second *iDose TR* demonstrating a favorable safety profile over a 12-month evaluation period.

iDose TR is a first-of-its-kind, long-duration, intracameral procedural pharmaceutical therapy designed to continuously deliver 24/7 therapeutic levels of a proprietary formulation of travoprost inside the eye for extended periods of time. *iDose TR* is intended to improve the standard of care by addressing the ubiquitous patient non-compliance issues and chronic side effects associated with topical glaucoma medications.

For more information about iDose TR and Full Prescribing Information, please visit www.iDoseTRhcp.com.

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 *iDose® TR (U.S.)*

iDose TR (travoprost intracameral implant) is a long duration prostaglandin analog approved for a single administration and indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). Made from medical-grade titanium, iDose TR is implanted through the trabecular meshwork and back wall of Schlemm's canal, directly into scleral tissue. Once implanted, 75 mcg of a novel, preservative-free, proprietary formulation of travoprost continuously elutes into the anterior chamber via membrane-controlled diffusion, allowing for 24/7 release of medication.

Indication for Use: iDose TR (travoprost intracameral implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

Dosage and Administration: For ophthalmic intracameral administration. The intracameral administration should be carried out under standard aseptic conditions.

Contraindications: iDose TR is contraindicated in patients with active or suspected ocular or periocular infections, patients with corneal endothelial cell dystrophy (e.g., Fuch’s Dystrophy, corneal guttatae), patients with prior corneal transplantation, or endothelial cell transplants (e.g., Descemet’s Stripping Automated Endothelial Keratoplasty [DSAEK]), patients with hypersensitivity to travoprost or to any other components of the product.

Warnings and Precautions: iDose TR should be used with caution in patients with narrow angles or other angle abnormalities. Monitor patients routinely to confirm the location of the iDose TR at the site of administration. Increased pigmentation of the iris can occur. Iris pigmentation is likely to be permanent.

Adverse Reactions: In controlled studies, the most common ocular adverse reactions reported in 2% to 6% of patients were increases in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperaemia, and reduced visual acuity.

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, our ability to successfully commercialize our iDose TR and Epioxa therapies, our ability to continue to generate sales of our commercialized products and develop and commercialize additional products, and the level of utilization and achievement of the repeat treatment algorithm used for the re-administration of the iDose TR. These and other risks, uncertainties, and factors related to Glaukos, and our business are described in detail under the caption "Risk Factors" and elsewhere in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which was filed with the SEC on October 31, 2025. Our filings with the SEC 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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