Glaukos Announces Positive Clinical Updates for its iDose® Sustained-Release Procedural Pharmaceutical Platform

2025-01-14

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 several positive clinical updates for its *iDose*® sustained-release procedural pharmaceutical platform, including:

- In a new 36-month follow-up analysis of its two Phase 3 pivotal clinical trials,*iDose TR* (travoprost intracameral implant) 75 mcg, an FDA-approved prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma, demonstrated sustained substantial IOP reductions as approximately 70% of*iDose TR*subjects remained well-controlled on the same or fewer IOP-lowering topical medications at 36 months after a single administration of*iDose TR*, versus 58% of timolol control subjects. In addition,*iDose TR* continued to demonstrate excellent tolerability and a favorable safety profile through 36 months across both Phase 3 trials.
- Glaukos has commenced a Phase 2b/3 clinical program for*iDose TREX*, its next-generation*iDose*sustained-release procedural pharmaceutical platform therapy.*iDose TREX* is designed to be very similar in size and form factor to the original*iDose TR*but has nearly twice the drug capacity.
- In a new 6-month follow-up analysis of a Phase 4 single-arm clinical study that evaluated 60 open-angle glaucoma patients,*iDose TR*implanted in combination with cataract surgery achieved a mean IOP reduction of 11.3 mmHg, or 44%, at 6 months compared to baseline.

“We are pleased to share these positive clinical updates on our *iDose* procedural pharmaceutical platform, helping to further advance our goal to position *iDose* as a transformative novel platform technology able to fundamentally improve the treatment paradigm for patients with glaucoma or ocular hypertension,” said Thomas Burns, Glaukos chairman and chief executive officer. “We continue to believe there is an important unmet clinical need and strong appetite within the ophthalmic community for safe, effective and sustained procedural pharmaceutical alternatives to traditional topical medications. These clinical updates leave us ideally positioned to advance our mission to transform vision therapies for the benefit of patients around the globe suffering from chronic eye diseases.”

Glaukos’ *iDose* sustained-release procedural pharmaceutical platform consists of a targeted, minimally-invasive, injectable implant designed to deliver therapeutic levels of medication from within the eye for

extended periods of time. The *iDose* platform is designed to address ubiquitous patient non-adherence and chronic side effects associated with topical medications by providing 24/7, long-duration, robust efficacy with minimal side effects. Given Glaukos' development success to date with *iDose TR* , the company continues to invest resources to expand its pharmaceutical development capabilities and develop future *iDose* solutions.

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 implant 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 rare 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, the extent to which we may obtain regulatory approval for iDose platform therapies or other investigational products, our ability to successfully commercialize such products, and the continued efficacy and safety profile of our products when commercially marketed as compared to their pre-approval clinical trial results. Historical, current and forward-looking sustainability-related statements may be based on standards for measuring progress that are still developing, internal controls and process that continue to evolve, and assumptions that are subject to change in the future. The information included in, and any issues identified as material for purposes of this document may not be considered material for SEC reporting purposes. In the context of this disclosure, the term "material" is distinct from, and should not be confused with, such term as defined for SEC reporting purposes. 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 Annual Report on Form 10-Q for the quarter ended September 30, 2024, which was filed with the Securities and Exchange Commission (SEC) on November 5, 2024. 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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Source: Glaukos Corporation