Glaukos Announces FDA Approval of iDose®TR (travoprost intracameral implant)

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Revolutionary, micro-invasive, injectable treatment for the full range of glaucoma disease severity

iDose TR was designed to usher in a new era of interventional glaucoma by enabling a proactive approach with a safe, effective, and durable therapy for patients in need

FDA approval based on robust Phase 3 clinical program consisting of two pivotal studies that randomized 1,150 subjects across 89 clinical sites

Glaukos to host a conference call on December 14, 2023, at 8:30 a.m. ET / 5:30 a.m. PT

ALISO VIEJO, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, announced today the U.S. Food and Drug Administration (FDA) approved its New Drug Application (NDA) for a single administration per eye of *iDose® TR* (travoprost intracameral implant) 75 mcg, a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG).

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.

“The FDA approval of *iDose TR* represents a significant milestone for Glaukos following an extensive pioneering journey since the inception of the original idea nearly 15 years ago. Today’s approval ushers in a new era of interventional glaucoma therapy by enabling a more proactive and reliable approach for patients in need,” said Thomas Burns, Glaukos chairman and chief executive officer. “We believe *iDose TR* can be a transformative, novel technology able to fundamentally improve the treatment paradigm for patients with open-angle glaucoma or ocular hypertension. We are grateful to the clinical investigators and study participants in the clinical trials for their instrumental roles in helping us reach this important advancement for glaucoma patient care. At Glaukos, we are relentlessly focused on delivering novel therapies for chronic eye diseases and now *iDoseTR* has the potential to redefine the standard of care for patients in the U.S. affected by open-angle glaucoma and ocular hypertension.”

“With the next generation of procedural pharmaceutical solutions for glaucoma such as *iDose TR*, we

now have a new tool that will confront the standard legacy practice of relying on topical drops, which are known to cause uncomfortable side effects and present a myriad of challenges such as treatment adherence, complex dosing regimens, and difficulty with self-administration," said John Berdahl, MD, clinician and researcher at Vance Thompson Vision. "The clinical data suggest that *iDoseTR* is not only effective with a favorable safety profile, but it has potential to relieve patients from the burdens of prescription eye drops for an extended period of time. I look forward to adding this novel therapy into my treatment toolbox for the benefit of my patients."

The FDA approval is based on results from two prospective, randomized, multicenter, double-masked, Phase 3 pivotal trials (GC-010 and GC-012) designed to compare the safety and efficacy of a single administration of one of two *iDose TR* models with different travoprost release rates (referred to as the fast- and slow-release *iDose TR* models, respectively) to topical timolol ophthalmic solution, 0.5% BID (twice a day), in reducing IOP in subjects with open-angle glaucoma or ocular hypertension. In total, the Phase 3 trials randomized 1,150 subjects across 89 clinical sites. The FDA approval and Phase 3 data referenced below is for the slow-release *iDose TR* model, consistent with the company's NDA submission and commercialization plans.

Both Phase 3 trials successfully achieved the pre-specified primary efficacy endpoints through 3 months and demonstrated a favorable tolerability and safety profile through 12 months. IOP reductions from baseline over the first 3 months were 6.6-8.4 mmHg in the *iDose TR* arm, versus 6.5-7.7 mmHg in the timolol control arm (mmHg range represents IOP reduction means across the six U.S. FDA pre-specified timepoints of 8 a.m. and 10 a.m. at Day 10, Week 6 and Month 3). Based on these outcomes, the FDA concluded in the prescribing information that *iDose TR* demonstrated non-inferiority to timolol ophthalmic solution in IOP reduction during the first 3 months. The FDA also noted that subsequently *iDose TR* did not demonstrate non-inferiority over the next 9 months.

At 12 months, 81% of *iDose TR* subjects were completely free of IOP-lowering topical medications across both trials. In both trials, *iDose TR* demonstrated excellent tolerability and subject retention with 98% of *iDose TR* subjects continuing in the trial at 12 months, versus 95% of timolol control subjects. In controlled studies, the most common ocular adverse reactions reported in 2% to 6% of *iDose TR* patients were increases in intraocular pressure, iritis, dry eye, and visual field defects, most of which were mild and transient in nature.

iDose TR is also supported by positive results from a Phase 2b clinical trial, which were recently highlighted in a peer-reviewed publication in *Drugs* (link here). The study authors concluded, "The travoprost intraocular implant demonstrated robust IOP-lowering and substantially reduced topical IOP-lowering medication burden for up to 36 months following a single administration, while maintaining a favorable safety profile."

Glaukos intends to commence initial commercial launch activities for *iDose TR* in the latter part of the first quarter of 2024. Glaukos has established a wholesale acquisition cost for *iDose TR* of $13,950, per dose (or implant).

Alongside the *iDose TR* approval announcement, Glaukos is proud to introduce the iDose Your Dose Initiative. For every *iDoseTR* sold, Glaukos pledges to make available an equal number of *iDoseTR* units for qualifying charitable donation requests in the U.S. and around the globe for recipients that satisfy independent eligibility requirements.

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

2023 and 2024 Revenue Guidance

The company reaffirms its 2023 net sales range of $307 million to $310 million and introduces preliminary 2024 net sales guidance range of $350 million to $360 million.

Webcast & Conference Call

The company will host a conference call and simultaneous webcast on December 14, 2023, at 8:30 a.m. ET (5:30 a.m. PT) to discuss the FDA approval of *iDose TR*. A link to the webcast is available on the company's website at http://investors.glaukos.com. To participate in the conference call, please dial 888-210-2212 (U.S.) or 646-960-0390 (international) and enter Conference ID 7935742. A replay of the webcast will be archived on the company's website following completion of the call.

About *iDoseTR*

iDoseTR (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.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical 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, and continues to develop a portfolio of technologically distinct and leverageable platforms to support ongoing pharmaceutical and medical device innovations. Products or product candidates for each of these platforms are designed to advance the standard of care through better treatment options across the areas of glaucoma, corneal disorders and retinal diseases.

iDose TR Indication and Important Safety Information

INDICATIONS AND USAGE

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 timing and extent to which we are able to obtain regulatory approval for investigational products, our ability to successfully commercialize and generate sales of our products, the ability to obtain and maintain adequate financial coverage and reimbursement for our products, our ability to properly train, and gain acceptance and trust from, ophthalmic surgeons in the use of our products, our ability to compete successfully in the pharmaceutical industry, which is highly competitive and rapidly changing, our compliance with federal and state laws and regulations for the approval, sale and marketing of our products and our manufacturing processes, the lengthy and expensive clinical trial process and the uncertainty of timing and outcomes from any particular clinical trial or regulatory approval processes, and the continued efficacy and safety profile of our products as reported in the pivotal trials and other clinical studies. 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, 2023, which was filed with the Securities and Exchange Commission (SEC) on November 1, 2023. 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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