



# Glaukos Announces FDA Acceptance of NDA Submission for *iDose TR*

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*PDUFA Date Set for December 22, 2023*

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, today announced it has received the "Day 74" notification from the U.S. Food and Drug Administration (FDA) acknowledging the previously submitted New Drug Application (NDA) for *iDose*<sup>®</sup> *TR* (travoprost intraocular implant) is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date for the completion of the FDA's review of the *iDose TR* NDA is set for December 22, 2023. This date reflects a standard 10-month review period and is consistent with management's expectations for the 505(b)(2) filing.

"The acceptance of the *iDose TR* NDA represents another important step in bringing this potential game-changing therapy one step closer to patients who may need a new treatment alternative," said Thomas Burns, Glaukos chairman and chief executive officer. "We look forward to working closely with the FDA throughout their review process and continue to 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."

The NDA submission includes data from two Phase 3 pivotal trials of *iDose TR*, which both successfully achieved the pre-specified primary efficacy endpoints through 3 months and demonstrated a favorable tolerability and safety profile through 12 months. In addition, the submission also includes data from the *iDose TR* exchange trial, which included a second administration of *iDose TR* and removal of the original *iDose TR*, with the second *iDose TR* administration demonstrating a favorable safety profile over a 12-month evaluation period.

*iDose TR* is a micro-invasive intraocular implant designed to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. *iDose TR* is designed to continuously deliver therapeutic levels of a proprietary formulation of travoprost from within the eye for extended periods of time. It is designed such that it can be removed and replaced with a new *iDose TR*, thus potentially offering a long-term dropless alternative to daily eye drop treatment. *iDose TR* is intended to address ubiquitous patient non-compliance and chronic side effects associated with topical IOP-lowering medications.

## **About Glaukos**



Glaukos ([www.glaukos.com](http://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.

## **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 obtain regulatory approval for investigational products such as iDose TR, our ability to successfully commercialize such products, the ability to obtain and maintain adequate financial coverage and reimbursement for this product, and the continued efficacy and safety profile of this product 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 March 31, 2023, which was filed with the Securities and Exchange Commission (SEC) on May 4, 2023. Our filings with the SEC are available in the Investor Section of our website at [www.glaukos.com](http://www.glaukos.com) or at [www.sec.gov](http://www.sec.gov). In addition, information about the risks and benefits of our products is available on our website at [www.glaukos.com](http://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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