



# Glaukos Achieves Pipeline Milestone with Enrollment Completion in Phase 3 Confirmatory Trial for Epioxa (Epi-on)

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*Enrollment Completion Achieved in Less Than Six Months from Trial Commencement, Ahead of Original Timing Expectations*

*Phase 3 Confirmatory Trial Results Together with Already-Completed First Phase 3 Trial Expected to Support Glaukos' Targeted NDA Submission for Epioxa by the End of 2024*

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 the completion of enrollment and randomization in its second Phase 3 confirmatory pivotal trial for Epioxa™ (*Epi-on*), its next-generation corneal cross-linking therapy for the treatment of keratoconus.

"The expeditious enrollment completion in the Epioxa Phase 3 confirmatory trial, which only commenced earlier this year, is a testament to the favorable risk-benefit profile of this next-generation therapy as well as our team's hard work in bringing this important therapy one step closer to patients suffering from keratoconus, a sight-threatening corneal disease," said Thomas Burns, Glaukos chairman and chief executive officer. "We appreciate the commitment and dedication of the clinical investigators, who played a vital role in helping to achieve this enrollment milestone ahead of our original timing expectations. We look forward to following these patients' outcomes as we target a U.S. New Drug Application (NDA) submission for Epioxa by the end of 2024."

The Epioxa multi-center, randomized, placebo and sham procedure controlled, Phase 3 confirmatory pivotal trial randomized 312 eyes and was designed to evaluate the safety and efficacy of Glaukos' Epioxa therapy in impeding the progression of, and/or reducing maximum corneal curvature (Kmax) in eyes with progressive keratoconus. Kmax is an objective measurement of the steepest corneal curvature based on corneal topography, where an increasing Kmax denotes corneal steepening and keratoconus disease progression. The study eyes were randomized in a 2:1 ratio to receive Epioxa therapy or placebo and sham procedure control treatment. The study's primary efficacy endpoint is the mean change in Kmax from baseline to Month 12. Based on an agreement with the U.S. Food and Drug Administration (FDA), the study will be considered a success if the difference between the treatment and control arm in the primary efficacy endpoint is statistically significant and the difference is  $\geq 1.0$  diopter (D).

Results from this second Phase 3 confirmatory pivotal trial together with the already-completed first Phase 3 pivotal trial are expected to support Glaukos' targeted NDA submission for Epioxa by the end of 2024. As a reminder, the U.S. FDA has confirmed Glaukos' first Phase 3 pivotal trial for Epioxa, which met the pre-specified primary efficacy endpoint, would be adequate to support the submission and review of an eventual NDA, in conjunction with this second Phase 3 trial.

As Glaukos continues to advance its clinical plans for Epioxa, it remains well-positioned to serve keratoconus patients with its first-generation corneal cross-linking therapy, Photrexa<sup>®</sup>, or *Epi-off*, which remains the only FDA-approved treatment shown to slow and halt the progression of keratoconus.

## **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 Epioxa, 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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