Glaukos Announces FDA Acceptance of NDA Submission for Epioxa™

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PDUFA Date Set for October 20, 2025

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 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 Epioxa™ (*Epi-on*), its next-generation corneal cross-linking iLink therapy for the treatment of keratoconus, a sight-threatening corneal disease, 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 Epioxa NDA is set for October 20, 2025. This date reflects a standard 10-month review period, which is consistent with the company’s expectations.

“The acceptance of the Epioxa NDA represents another important step in being able to provide keratoconus patients and the ophthalmic community with the first FDA-approved, non-invasive corneal cross-linking drug therapy that does not require removal of the corneal epithelium, the outermost layer of the front of the eye,” 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 Epioxa , which is designed to reduce procedure times, improve patient comfort and shorten recovery time, represents a potentially meaningful advancement in the treatment paradigm for patients suffering from keratoconus.”

The NDA submission includes data from two Phase 3 pivotal trials of Epioxa, which both successfully achieved the pre-specified primary efficacy endpoints and demonstrated favorable tolerability and safety profiles.

Glaukos’ corneal cross-linking iLink therapies use proprietary, bio-activated drug formulations designed to strengthen corneal tissue and halt progression of keratoconus. Typically diagnosed in a patient’s teenage years, keratoconus is a debilitating eye condition characterized by progressive thinning and weakening of the cornea. If left untreated, keratoconus can lead to loss of vision and even blindness and is one of the leading causes of corneal transplant (penetrating keratoplasty) in the United States. Approximately 90% of cases of keratoconus are bilateral and as many as 20% of patients ultimately require a corneal transplant. Conventional keratoconus treatments such as eyeglasses or contact lenses address symptoms but Glaukos’ first-generation iLink therapy, known as Photrexa® , or *Epi-off* , is the first and only FDA-approved therapy that has been shown to slow or halt disease progression. There are more than 300 peer-reviewed publications supporting the performance and safety of

Glaukos' iLink therapy.

Epioxa utilizes a proprietary, novel drug formulation designed to penetrate the epithelial layer of the cornea, a stronger UV-A irradiation protocol and supplemental oxygen to enhance cross-linking. If approved, the company anticipates Epioxa would be the first FDA-approved, non-invasive corneal cross-linking therapy that does not require removal of the corneal epithelium, the outermost layer of the front of the eye.

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 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.

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 Epioxa or other investigational products, our ability to successfully commercialize such products, the continued efficacy and safety profile of our products when commercially marketed as compared to their pre-approval clinical trial results, and the extent to which the FDA completes its review of the Epioxa NDA by October 20, 2025, particularly in view of recent and anticipated actions by the current administration that could adversely affect staffing levels and funding for the FDA and as a result, prevent or delay marketing approvals. 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 Securities and Exchange Commission (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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, which was filed with the SEC on November 5, 2024, and our Annual Report on Form 10-K for the year ended December 31, 2024, which is expected to be filed with the SEC by March 3, 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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