



Glaukos Announces FDA Approval of Epioxa™

2025-10-20

Epioxa Provides the Ophthalmic Community and Patients with the First and Only FDA-Approved, Incision-Free, Topical Drug Therapy for Keratoconus

Epioxa Represents a Novel, Groundbreaking Therapy for Patients Afflicted by This Sight-Threatening Rare Disease

Epioxa Expected to Be Commercially Available in Q1 2026

Aliso Viejo, CA – October 20, 2025 – 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, announced today the U.S. Food and Drug Administration (FDA) approved its Epioxa™ HD / Epioxa™ (“Epioxa”) New Drug Application (NDA). Epioxa is a groundbreaking advancement in corneal cross-linking for the treatment of keratoconus, a rare, sight-threatening disease that is currently far too often undiagnosed and untreated.

Epioxa represents a transformative innovation in keratoconus care, offering an incision-free alternative to traditional corneal cross-linking procedures as it does not require the removal of the corneal epithelium, the outermost layer of the front of the eye. This novel, oxygen-enriched topical therapeutic, bioactivated by UV light, is designed to eliminate the pain associated with removal of the epithelium, streamline the procedure, and minimize recovery, all while delivering clinically meaningful outcomes and exceptional value to patients, providers, and the healthcare system. Epioxa is based on two formulations, Epioxa HD and Epioxa, that are sequentially administered during the cross-linking procedure followed by UV activation in an oxygen-enriched environment.

“The FDA approval of Epioxa ushers in a new standard-of-care for patients suffering from keratoconus with the first FDA-approved topical drug therapy that does not require removal of the corneal epithelium,” said Thomas Burns, Glaukos chairman and chief executive officer. “Epioxa is designed to significantly improve patient comfort and minimize recovery time, representing a game-changing new treatment for patients suffering from keratoconus. We appreciate the clinical investigators and study participants in the clinical trials for their instrumental roles in helping us reach this important advancement. This approval marks a major milestone in our mission to improve patient access to sight-saving therapies, and we are excited to bring this transformative therapy to market for the benefit of patients.”

“Keratoconus is currently an underdiagnosed and undertreated disease. For keratoconus patients who are fortunate enough to be diagnosed, the current standard-of-care requires removal of the epithelium, the top layer of the cornea. The pain and extended healing time associated with the current surgical procedure are major barriers to adoption,” said W. Barry Lee, MD, corneal specialist at Eye Consultants of Atlanta and President of the Cornea Society. “As an incision-free treatment that does not require removal of the epithelium, I expect the newly approved Epioxa treatment to address both of these major concerns.”

The FDA approval of Epioxa is based on results from two prospective, randomized, multicenter, double-masked, Phase 3 pivotal trials that randomized a total of over 400 patients. Both trials successfully achieved their pre-specified primary efficacy endpoints and demonstrated favorable tolerability and safety profiles.

Glaukos intends for Epioxa to be commercially available in the first quarter of 2026. With this approval, Glaukos plans to make substantial investments in patient awareness and access while addressing the longstanding challenges of underdiagnosis and undertreatment that have affected this rare disease patient community. These efforts will be focused on supporting patients and families across every step of the journey, from awareness to diagnosis and treatment. Key initiatives include streamlined patient access support programs, a co-pay assistance program to reduce financial barriers, integrated healthcare professional (HCP) and patient-centric strategies to improve education and engagement, and broad awareness and detection programs aimed at earlier and more widespread screening for and diagnosis of the disease.

Keratoconus is a debilitating eye condition characterized by progressive thinning and weakening of the cornea that is often most aggressively advancing in patients under the age of 30. If left untreated, keratoconus can lead to loss of visual function and even blindness and is one of the leading causes of corneal transplants (penetrating keratoplasty) in the United States. Approximately 90% of cases of keratoconus are bilateral and as many as 20% of untreated keratoconus patients ultimately require a corneal transplant. Conventional keratoconus treatments such as eyeglasses or contact lenses address visual symptoms only and do not slow or halt underlying disease progression.

Glaukos' first-generation corneal cross-linking therapy, known as Photrexa[®] Viscous / Photrexa[®], which requires removal of the corneal epithelium, received U.S. FDA approval in 2016 as an orphan drug and has since been the first-and-only FDA-approved corneal cross-linking therapy for the treatment of keratoconus. There are more than 300 peer-reviewed publications supporting the performance and safety of Glaukos' cross-linking therapies.

Glaukos plans to provide additional details on the FDA approval of Epioxa and related matters as part of its upcoming third quarter 2025 financial results conference call scheduled for Wednesday, October 29, 2025, at 4:30 p.m. ET. 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 800-715-9871 (U.S.) or 646-307-1963 (international) and enter Conference ID 5255602. A replay of the webcast will be archived on the company's website following completion of the call.

For more information about Epioxa HD / Epioxa and Full Prescribing Information, please visit www.Epioxa.com.

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 rarely diagnosed 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.

Epioxa HD / Epioxa Indication and Important Safety Information

Indication: EPIOXA™ HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and EPIOXA™ (riboflavin 5'-phosphate ophthalmic solution) 0.177% are photoenhancers indicated for use in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O2n™ System and the Boost Goggles®.

Dosage and Administration: EPIOXA HD and EPIOXA are for topical ophthalmic use. NOT for injection or intraocular use. EPIOXA HD and EPIOXA are supplied in single-dose syringes. Discard opened syringes after use. EPIOXA HD and EPIOXA are for use with the O2n System and Boost Goggles only. Refer to the O2n System Operator's Manual and Boost Goggles User Guide for device instructions.

Contraindications: EPIOXA HD and EPIOXA are contraindicated in patients with known hypersensitivity to benzalkonium chloride or any ingredients in EPIOXA HD and EPIOXA. Epithelium-on corneal collagen cross-linking is contraindicated in aphakic and pseudophakic patients without a UV-blocking intraocular lens.

Warnings and Precautions: Corneal collagen cross-linking should be used with caution in patients with a history of herpetic keratitis due to the potential for reactivation of herpes keratitis.

Adverse Reactions: The most common adverse reaction was conjunctival hyperaemia (31%). Other adverse reactions, occurring in 5% to 25% of eyes included: corneal opacity (haze), photophobia, punctate keratitis, eye pain, eye irritation, increased lacrimation, corneal epithelium defect, eyelid oedema, corneal striae, visual acuity reduced, dry eye, and anterior chamber flare.

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, our ability to successfully commercialize Epioxa HD / Epioxa and other investigational products, including by maximizing patient access and addressing the challenges of underdiagnosis and undertreatment, and the continued efficacy and safety profile of our products when commercially marketed as compared to their pre-approval clinical trial results. 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 June 30, 2025, which was filed with the SEC on August 4, 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.

Media Contact:

Michele Gray

(917) 449-9250

michele@mgraycommunications.com

Investor Contact:

Chris Lewis

Vice President, Investor Relations & Corporate Affairs

(949) 481-0510

clewis@glaukos.com