



Glaukos Announces Positive Clinical Updates for Several Corneal Health Pipeline Programs

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Commencement of Subject Enrollment in Epioxa™ Phase 3 Confirmatory Trial

Promising Phase 2a Results for GLK-301 (iLution – Dry Eye Disease) Support Planned Phase 2b Study to Commence in 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 positive clinical updates for several of its Corneal Health pipeline programs, including the commencement of subject enrollment in a second Phase 3 confirmatory trial for Epioxa™ (*Epi-on*™), and promising initial results from the company's Phase 2a clinical trial for GLK-301 (*iLution* - Dry Eye Disease).

"These clinical updates represent meaningful milestones for two of our key Corneal Health pipeline programs and we look forward to continuing to advance both of these important programs forward in 2023," said Thomas Burns, Glaukos chairman and chief executive officer. "We continue to successfully invest in and advance our 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."

Glaukos commenced subject enrollment in its second Phase 3 confirmatory pivotal trial for Epioxa (*Epi-on*), its next-generation corneal cross-linking therapy for the treatment of keratoconus. Glaukos plans to randomize approximately 290 subjects in this trial and is targeting enrollment completion by the end of 2023. As a reminder, the U.S. Food and Drug Administration (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 New Drug Application (NDA), in conjunction with this second 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[®], or *Epi-off*™, which remains the only FDA-approved treatment shown to slow and halt the progression of keratoconus.

Glaukos also announced promising topline results from its Phase 2a first-in-human clinical trial for GLK-301 (*iLution* – Dry Eye Disease (DED)) for the signs and symptoms of DED. GLK-301 is a sterile ophthalmic topical cream to be applied to the eyelids for the treatment of signs and symptoms of DED. The trial's endpoints included the evaluation of multiple signs and symptoms characteristic of DED. Topline Phase 2a outcomes for GLK-301 demonstrated improvement in the quality of tear film (tear

break-up time) with corresponding improvement in quality of vision (reduction in blurred vision). Based on these encouraging observations, Glaukos plans to advance GLK-301 into a Phase 2b clinical trial targeted to begin in 2023.

The Phase 2a multi-center, randomized, double-masked, placebo-controlled trial enrolled 218 subjects across clinical sites in the United States and was designed to evaluate the safety and efficacy of three different dose levels of GLK-301 administered twice daily (BID) to the eyelids versus placebo over 28 days, followed by a 14-day safety follow-up period, in subjects diagnosed with DED.

GLK-301 is the first investigational drug candidate utilizing Glaukos' iLution platform's patented cream-based drug formulations that are applied to the outer surface of the eyelid for dropless transdermal delivery of pharmaceutically active compounds for the treatment of eye disorders. The cream formulation acts as a depot allowing pilocarpine to be delivered through the dermis of the eyelid to the eye.

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.

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 or GLK-301, 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 September 30, 2022, which was filed with the Securities and Exchange Commission (SEC) on November 4, 2022. 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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