



# Glaukos Announces First Patient Enrolled in Phase 2 Clinical Trial for Dry Eye Disease

2022-01-11

SAN CLEMENTE, 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 that it has enrolled the first patient into a Phase 2 clinical trial of GLK-301 for the treatment of signs and symptoms of Dry Eye Disease (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. GLK-301's active pharmaceutical ingredient is pilocarpine.

The Phase 2 multi-center, randomized, double-masked, placebo-controlled trial is 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 patients diagnosed with DED. Endpoints will include standard signs and symptoms characteristic of DED. The company anticipates it will enroll approximately 200 DED patients in the study across clinical sites in the United States. Additionally, approximately 20 patients with a diagnosis of DED due to Sjogren's Syndrome will also be enrolled.

"Dry Eye Disease is a common ocular inflammation condition with high unmet clinical need, representing one of the world's largest ophthalmic markets worldwide. Today's announcement represents a significant milestone in the development of our iLution platform and for our company," said Thomas Burns, Glaukos president and chief executive officer. "We believe our iLution platform has the potential to address the major unmet need for patients suffering from Dry Eye Disease and other chronic eye diseases by providing an effective, easy to administer, safe, dropless transdermal therapeutic. We are delighted to have the opportunity to explore what GLK-301 can do for DED patients in our Phase 2 trial."

GLK-301 is a sterile ophthalmic topical cream to be applied to the eyelids for the treatment of signs and symptoms of DED. 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](http://www.glaukos.com)) is an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. The company pioneered Micro-Invasive Glaucoma Surgery, or MIGS, to revolutionize the traditional

glaucoma treatment and management paradigm. Glaukos launched the *iStent*<sup>®</sup>, its first MIGS device, in the United States in 2012, its next-generation *iStent inject*<sup>®</sup> device in the United States in 2018, and most recently, the *iStent inject W* device in 2020. In corneal health, Glaukos' proprietary suite of single-use, bio-activated pharmaceuticals are designed to strengthen, stabilize and reshape the cornea through a process called corneal collagen cross-linking to treat corneal ectatic disorders and correct refractive conditions. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

## 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 are successful in our clinical trials evaluating the safety and efficacy of iLution, the extent to which we may obtain regulatory approval for iLution or other investigational products, our ability to successfully commercialize such products, the ability to obtain and maintain adequate financial coverage and reimbursement for our products, and the continued efficacy and safety profile of our products. 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, 2021, which was filed with the Securities and Exchange Commission (SEC) on November 8, 2021. Our filings with the Securities and Exchange Commission 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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Source: Glaukos Corporation