



Glaukos Announces First Patient Enrolled in Phase 2 Clinical Trial for Presbyopia

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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-302 for the treatment of presbyopia. GLK-302 is the second 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-302'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-302 administered twice daily (BID) to the eyelid versus placebo over 28 days, for improving mesopic, high-contrast, binocular distance corrected near visual acuity (DCNVA) while not deteriorating binocular best corrected distance visual acuity (BCDVA) in presbyopic patients. The company anticipates it will enroll approximately 120 presbyopic patients in the study across clinical sites in the United States.

"We believe iLution has the potential to address the major unmet need for presbyopic patients by providing an effective, easy to administer, safe, dropless transdermal therapeutic. 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. "The dosing of the first patient in the Phase 2 study brings us one step closer to an innovative near vision solution for the millions of patients who suffer from presbyopia. We are privileged to have the opportunity to explore what GLK-302 can do for presbyopic patients in our Phase 2 trial."

Presbyopia is a natural part of aging due to the hardening of the eye's crystalline lens over time, resulting in a loss of lens elasticity or the ability of the lens to change shape in order to focus incoming light on the retina. With this loss of flexibility, eyes are less able to adjust properly to focus on near objects. Presbyopia usually becomes noticeable around the age of 40 and there is no proven way to stop or reverse the progression of presbyopia.

GLK-302 is a sterile ophthalmic topical cream to be applied to the eyelid for the treatment of presbyopia. 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 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*[®], its first MIGS device, in the United States in 2012, its next-generation *iStent inject*[®] 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 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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