Glaukos Announces Positive Phase 3 Trial Results for iLink™ Epi-on Investigational Therapy That Met the Primary Efficacy Endpoint

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Study Met Primary Efficacy Endpoint with Statistically Significant Improvement in Maximum Corneal Curvature at 6 Months

Epi-on Treatment Demonstrated the Ability to Halt or Reduce the Progression of Keratoconus versus Observed Disease Progression in a Placebo-Control Arm

Data Suggest Epi-on Has the Potential to Provide the Ophthalmic Community and Keratoconus Patients with the First Non-Invasive, Bio-Activated Drug Therapy Alternative for Keratoconus

Data to Serve as the Basis for U.S. NDA Submission in 2022

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 U.S. Phase 3 pivotal trial results for its next-generation corneal cross-linking iLink™ therapy for the treatment of keratoconus, known as Epi-on, met the study's primary efficacy endpoint, demonstrating a statistically significant improvement in maximum corneal curvature (Kmax) at 6 months from baseline between the treated and placebo-controlled arms. Kmax is an objective measurement of the steepest corneal curvature based on corneal topography, where an increasing Kmax denotes corneal steepening and keratoconus disease progression.

The Epi-on multi-center, randomized, placebo-controlled, Phase 3 pivotal trial was designed to evaluate the safety and efficacy of Glaukos' iLink Epi-on therapy in impeding the progression of, and/or reducing Kmax in eyes with progressive keratoconus. The study eyes were randomized in a 2:1 ratio to receive Epi-on therapy or placebo-control treatment. The study's primary efficacy endpoint is a difference of ≥ 1 diopter (D) between treatment and control arms in the mean change in Kmax from baseline to Month 6. The study enrolled 279 eyes across 14 clinical sites in the United States, including 189 eyes randomized to the treatment arm and 90 eyes randomized to the control arm. Following the completion of the 6-month primary efficacy and safety evaluation period, the patients randomized to placebo were able to cross-over and receive the Epi-on treatment. All patients were then followed for another 6 months for safety and efficacy evaluation.

Topline summary results and observations from the Phase 3 clinical trial are as follows:

- The Epi-on Phase 3 clinical trial achieved its primary efficacy outcome by demonstrating Kmax treatment effect of -1.0D (p = 0.0004), determined as prospectively defined least square mean Kmax change from baseline in treated arm versus placebo arm at Month 6 study endpoint.
- The treatment effect of -1.0D (p = 0.0004) composed of improvement in Kmax by 0.2D in the treated arm and worsening in Kmax by 0.8D in the placebo-controlled arm, thus demonstrating the ability of Epi-on to halt or reduce the keratoconus disease progression in the treated arm during the 6-month primary efficacy evaluation period.
- 98% of patients randomized to the placebo-control arm elected to cross-over to Epi-on treatment after the 6-month primary efficacy evaluation period. For these patients that crossed-over to treatment, data showed Kmax improvement mean change of 0.3D (p = 0.053) at 6 months following treatment. Additionally, patients randomized to treatment at the start of the study continued to improve during the safety follow-up period from Month 7 to Month 12 post-treatment with Kmax treatment effect of -1.1D (p = 0.0001) at Month 12.
- The treatment was generally well-tolerated, with 97% of enrolled treatment patients completing the 12-month trial, compared to 96% of enrolled control patients. No patients discontinued early due to an adverse event. The most common ocular adverse events observed in treatment patients were conjunctival hyperemia, corneal opacity, photophobia, punctate keratitis, eye pain, eye irritation, increased lacrimation, eyelid oedema, corneal striae and dry eye. The majority of adverse events reported were mild and transient in nature. There was a single case of a drug-related serious adverse event (corneal haze). There was no evidence of treatment-related systemic effects reported in the study and there was no change in corneal endothelial cell counts over the course of the entire trial.

“We are excited to announce these positive Phase 3 results that met the study’s primary efficacy endpoint and demonstrated the ability of Epi-on to halt or reduce the progression of keratoconus, a progressive, sight-threatening corneal disease. These results further underscore our view that Epi-on may provide the ophthalmic community and keratoconus patients with the first non-invasive, bio-activated drug treatment alternative designed to reduce procedure time, improve patient comfort and shorten recovery time,” said Thomas Burns, Glaukos president and chief executive officer. “We appreciate the commitment and dedication of the clinical investigators, who play a vital role in bringing new innovations to patients suffering from keratoconus and at risk for significant vision loss. We look forward to working cooperatively with the FDA as we prepare for an upcoming regulatory submission in 2022.”

Glaukos’ iLink therapy uses proprietary, bio-activated, single-use drug formulations to strengthen corneal tissue and halt progression of keratoconus, a degenerative corneal ectatic disease that affects as many as 1.1 million eyes in the United States. 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 the leading cause of corneal transplant (penetrating keratoplasty) in the United States. Approximately 90% of cases 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 Epi-off, is the first and only FDA-approved therapy that has been shown to slow or halt disease progression. There are approximately 183 peer-reviewed publications supporting the performance and safety of Glaukos’ iLink therapy.

Epi-on, which is designed to reduce procedure times, improve patient comfort and shorten recovery time, utilizes a proprietary, novel drug formulation designed to penetrate the epithelial layer of the cornea, a stronger UVA irradiation protocol and the ability to deliver increased levels of supplemental oxygen to enhance cross-linking. If approved, the company anticipates Epi-on would be the first FDA-approved, non-invasive corneal cross-linking therapy that does not require removal of the epithelium,

the outermost layer of the eye.

The Phase 3 trial results are expected to support Glaukos' U.S. NDA submission in 2022 and the company is targeting U.S. FDA approval for Epi-on in 2023.

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 continued efficacy and safety profile of our products, the extent to which we may obtain regulatory approval for the Epi-on or other investigational products, our ability to successfully commercialize such products, 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 September 30, 2020 filed with the Securities and Exchange Commission on November 5, 2020 and will also be included in our Annual Report on Form 10-K for 2020, which we expect to file on or before March 1, 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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