



Glaukos Announces Positive Results for iDose TR Exchange Trial, Highlighting Favorable Safety and Tolerability

2023-01-10

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 results for a prospective, multi-center clinical trial designed to evaluate the safety of the surgical exchange procedure for *iDose*[®] *TR* (*travoprost intraocular implant*) in subjects who had previously been administered an *iDose TR* in the Phase 2b clinical trial (referred to as the "exchange trial").

Results from the exchange trial demonstrated a second administration of *iDose TR* and removal of the original *iDose TR* implant was safe and well-tolerated, with the second *iDose TR* demonstrating a favorable safety profile over a 12-month evaluation period. Additionally, no subject in the exchange trial exhibited a greater than 30% endothelial cell loss over the extended evaluation period of more than five years on average. Glaukos plans to include the exchange trial's positive data set in its upcoming U.S. Food and Drug Administration (FDA) New Drug Application (NDA) submission targeted for the first quarter of 2023.

"We are pleased to clinically confirm the *iDoseTR* exchange procedure is safe and facile. We look forward to including these positive data in our upcoming NDA submission to further support the safety and tolerability of redosing *iDose TR* patients over time," said Thomas Burns, Glaukos chairman and chief executive officer. "We continue to believe *iDose TR* can be a transformative novel technology able to fundamentally improve the treatment paradigm for patients with glaucoma."

The exchange trial, based upon an agreement with the FDA, was designed to evaluate the feasibility and safety of a surgical exchange procedure of *iDose TR* in subjects who were previously implanted with *iDose TR* as part of the *iDose TR* Phase 2b clinical trial. A total of 33 subjects were enrolled and 32 subjects (97.0%) completed the trial. The average time from administration of the first implant (first implantation cycle) in the Phase 2b trial to the time of the exchange procedure of the second implant in the exchange trial (second implantation cycle) was 4.2 years. The exchange trial subjects were then followed for an additional year following the second implantation cycle, for an overall extended evaluation period average of 5.2 years.

During the exchange procedure using the pre-loaded injector, the surgeon inserted and anchored the new implant into the sclera at least one clock hour away from the previous implant from the first implantation cycle, and using the now-empty inserter, grasped and removed the previous implant.

Administered during a micro-invasive procedure, the *iDose TR* contains a novel formulation of travoprost, a prostaglandin analog used to lower intraocular pressure. Once all the travoprost is released, the *iDose TR* is designed to be removed and replaced with a new *iDose TR*, thus potentially offering a dropless alternative to daily eye drop treatment.

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 *iDose TR*, 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.

Media Contact:

Cassandra Dump
(619) 971-1887

Cassy.dump@precisionvh.com

Investor Contact:

Chris Lewis
Vice President, Investor Relations & Corporate Affairs
(949) 481-0510

clewis@glaukos.com

Source: Glaukos Corporation