Eyenovia Provides Clinical and Scientific Update on FDA-Approved Products Mydcombi™ and Clobetasol Propionate Ophthalmic Suspension

April 25, 2024 at 7:00 AM EDT

Company announces results from a Phase IV study of Mydcombi designed to characterize the efficacy and duration of the lowest deliverable dose (one 8µL spray per eye)

Also announces upcoming ARVO presentation on the unique technology behind clobetasol that allows for future ophthalmic suspensions to be dispensed with the Optejet®

NEW YORK, April 25, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company, today provided an update on its two FDA-approved products.

Phase IV study of Mydcombi (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

Eyenovia announced today results from a Phase IV study of Mydcombi® designed to characterize the lowest deliverable dose for mydriasis (pupil dilation). Mydcombi is the only FDA-approved fixed dose combination of tropicamide and phenylephrine hydrochloride ophthalmic spray 1%/2.5%, and the first FDA-approved product in the Optejet®.

Current mydriatic eye drops used during eye exams have several limitations, including potential cross-contamination, difficulty instilling in patients with limited mobility, and in some patients, tolerability and safety issues. Phenylephrine, in higher amounts, has been known to cause serious potential systemic cardiovascular side effects in older patients, particularly those with high blood pressure.

This Phase IV study was designed to determine the efficacy and duration of effect of the lowest deliverable dose of Mydcombi for pupil dilation. Twenty-nine subjects were treated with a half dose of Mydcombi (8µL per eye) and evaluated at the end of 2023 at the State University of New York School of Optometry by Dr. Denise Pensyl, OD.

Study highlights:

- At 30 minutes post dose, clinically relevant pupil dilation was achieved in approximately 67% of patients;
- By 60 minutes, that percentage increased to 86%;
- The majority of patients returned to a pupil size of less than 5mm between 3.5 and 6 hours post-instillation, with 93% reaching that point by 6 hours;
- Administering a lower 8 microliter volume was well tolerated with minimal adverse events reported.

“The results of this study highlight the favorable efficacy and tolerability of Mydcombi dispensed through the Optejet,” stated Michael Rowe, Eyenovia’s Chief Executive Officer. “Notably, dilation was already dissipating by 3.5 hours post-instillation, which is similar to published studies of dilating eye drops followed by the use of a mydriasis reversal agent. These results suggest that for patients in which the lowest deliverable dose of tropicamide and phenylephrine may be desired, the precision and flexibility of the Optejet technology may be an option for eye care professionals and their patients.”

Eyenovia plans to present the full data set at an upcoming medical meeting this year.

Results of this study can be found at: https://clinicaltrials.gov/study/NCT06217796

ARVO Presentation

Eyenovia also announced today that the company will deliver a presentation at the Association for Research in Vision and Ophthalmology (ARVO) 2024 Annual Meeting, which is being held May 5-9, 2024, in Seattle, WA.

The presentation will detail results from a study demonstrating that Formosa Pharmaceuticals’ Active Pharmaceutical ingredient Nanoparticle Technology (APNT™) can improve solubility and bioavailability of topical ophthalmic medicationsEyenovia licensed clobetasol propionate ophthalmic suspension 0.05%, which leverages APNT technology, from Formosa in August 2023, and clobetasol was subsequently approved by the U.S. Food and Drug Administration (FDA) for the treatment of post-operative inflammation and pain in March 2024. Eyenovia is planning to launch clobetasol later this summer, as a complement to Mydcombi, the company’s commercially available mydriasis agent.

“The data presented at this year’s ARVO Annual Meeting further demonstrates that APNT represents an exciting new drug manufacturing technology with the potential to deliver suspensions through our Optejet dispenser,” continued Mr. Rowe. “We look forward to incorporating this technology in future products, as well as launching clobetasol which uses APNT. Clobetasol will be the first new ophthalmic steroid in many years, participating in a market estimated to be worth in excess of $1.3 billion annually.”

Presentation details:

Title:	**Evaluation of APNT™ Nanoparticle Formulation in Ophthalmic Medications**
Presentation Number:	3991 - B0035
Date:	May 7, 2024
Time:	3:30 PM to 5:15 PM PT (6:30 PM to 8:15 PM ET)

Additional information on the ARVO meeting can be found here: https://www.arvo.org/annual-meeting/

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi for mydriasis, as well as the ongoing late-stage development of medications in the Optejet device for presbyopia and myopia progression. For more information, visit Eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

Forward-Looking Statements

Except for historical information, all the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology, and the timing for availability and sales growth of our approved products. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; intellectual property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products and product candidates; and our competitive position.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

IMPORTANT SAFETY INFORMATION: Clobetasol Propionate Ophthalmic Suspension 0.05% is indicated for the treatment of post-operative inflammation and pain following ocular surgery. **CONTRAINDICATIONS:** Most active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. **WARNINGS AND PRECAUTIONS:** Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, IOP should be monitored. Cataracts: Prolonged use of corticosteroids may result in posterior subcapsular cataract formation. Delayed Healing: The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. Corneal and Scleral Melting: In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining. Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated. Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate. **ADVERSE REACTIONS:** Ocular adverse reactions occurring in ≥ 1% of subjects in clinical studies who received clobetasol propionate ophthalmic suspension 0.05% included eye inflammation (2%), corneal edema (2%), anterior chamber inflammation (2%), cystoid macular edema (2%), intraocular pressure elevation (1%), photophobia (1%) and vitreous detachment (1%). Many of these reactions may have been the consequence of the surgical procedure. **PLEASE GO TO CLOBETASOLBID.COM FOR FULL PRESCRIBING INFORMATION**

IMPORTANT SAFETY INFORMATION: MYDCOMBI (tropicamide 1% and phenylephrine HCl 2.5%) ophthalmic spray is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired.
CONTRAINDICATIONS: Known hypersensitivity to any component of the formulation. **WARNINGS AND PRECAUTIONS:** Not for Injection: Topical ophthalmic use. Significant Elevations in Blood Pressure: Caution in pediatric patients less than 5 years of age, and in patients with cardiovascular disease or hyperthyroidism. In patients at high risk, monitor blood pressure post treatment. Central Nervous System Disturbances: Caution in pediatric patients where rare incidences of central nervous system disturbances have been reported. Intraocular Pressure: May produce a transient elevation. Rebound Miosis: Reported 1 day after administration. **DRUG INTERACTIONS:** Atropine-like Drugs: May exaggerate the adrenergic pressor response. Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors. Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents. **ADVERSE REACTIONS**: Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics. Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and

muscle rigidity have been reported with the use of tropicamide. To report **SUSPECTED ADVERSE REACTIONS**, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 www.fda.gov/medwatch

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