Eyenovia Announces Positive Topline Results from VISION-1 Phase 3 Clinical Study of MicroLine for the Treatment of Presbyopia

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Primary endpoint was achieved with well-tolerated micro-array print (MAP™) safety profile

Upcoming key 12 month milestones include Mydcombi PDUFA; Vision 2 Phase 3 trial results and completion of enrollment for CHAPERONE Phase 3 trial

NEW YORK, May 25, 2021 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of MAP™ therapeutics, today announced that its VISION-1 study evaluating the company's proprietary pilocarpine formulation, MicroLine, for the temporary improvement of near vision in adults with presbyopia, achieved its primary endpoint. Preparations are underway for a second Phase 3 registration study, VISION-2. These studies are required for FDA approval and will serve as the basis for a planned New Drug Application (NDA) submission to FDA. VISION-1 results will be presented at a future ophthalmic-focused medical meeting.

The VISION-1 study evaluated the safety and efficacy of Eyenovia's 1% and 2% pilocarpine Micro-Array Print formulations versus placebo, all administered via the company's proprietary Optejet® dispenser. VISION-1 is the third Phase 3 study demonstrating the utility of the company's MAP technology in improving the therapeutic index of topical ophthalmic drugs.

Key highlights from the study include:

- VISION-1 met its primary endpoint with a statistically significant proportion of subjects treated with a therapeutic dose of MicroLine showing a three-line or more improvement in distance corrected near visual acuity (DCNVA) versus placebo in low light conditions at two hours post-treatment.
- MicroLine was very well tolerated. Adverse events were all mild in nature and there were no serious adverse events.
- In a post-study survey, 70% of study participants reported strong interest in using MicroLine for near vision improvement should it be approved. These patients said they would expect to use the product three to four times per week on average.

"We are extremely pleased at the success of our VISION-1 study, marking another major milestone for our Micro-Array Print platform technology," stated Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "Along with plans for VISION-2 in the coming months, we continue to prepare for the potential FDA approval of MydCombi™ for mydriasis in the fourth quarter and full enrollment of the CHAPERONE study for pediatric myopia shortly thereafter."

Presbyopia is the age-related, progressive hardening of the eye's lens, making it difficult for the clear lens of the eye to change shape. Presbyopia causes blurred near vision and is often corrected with eyeglasses or "readers," contact lenses or surgery. In the 40 to 55 age group, approximately 18 million people in the U.S. are presbyopic, suggesting a multi-billion U.S. market opportunity for MicroLine, if approved.

Dr. Robert Weinreb, Distinguished Professor and Chair of Ophthalmology at the University of California, San Diego, added, "Besides being a new option for presbyopic patients, MicroLine also may improve community eye health. Presbyopic patients now often obtain reading glasses without a comprehensive eye examination. With the potential future availability of MicroLine, such patients instead might seek an eye examination in order to obtain a prescription for the product."

"Optometrists know that presbyopic patients are seeking more options to help them perform common activities, such as reading a menu or glancing at their smart phone," said April Jasper, OD FAAO and Eyenovia Medical Monitor. "Many of these patients simply purchase reading glasses without the benefit of a regular eye exam and end up unhappy being dependent on them and because they can make them look older. The ability to have an option such as MicroLine could address a common request from patients for the freedom to not have to wear glasses in certain situations."

About the VISION Trials
The VISION trials are Phase 3, double-masked, placebo-controlled, cross-over superiority trials that will enroll participants with presbyopia. The primary endpoint is binocular distance corrected near visual acuity. MicroLine is intended for the "on demand" improvement of near vision in people with presbyopia.

About MicroLine
Eyenovia's MicroLine is a proprietary microdosed formulation of pilocarpine for presbyopia that is delivered via the Company's Optejet® dispenser. Providing high precision microdosing at approximately 1/5th the drug volume of a traditional eye dropper, the Optejet is designed to deliver targeted, consistent doses more conveniently than typical eyedroppers.

About MydCombi™
MydCombi is Eyenovia's first-in-class fixed-combination micro-formulation product (tropicamide 1% - phenylephrine 2.5%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 80 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed for use without anesthetic, Eyenovia is developing MydCombi to help improve the efficacy and tolerability of pharmacologic mydriasis.

About Eyenovia, Inc.
Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more information, visit www.eyenovia.com.

Forward-Looking Statements
Except for historical information, all of 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. 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 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 (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative 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 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.

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