Eyenovia highlights Recent Progress in Three Phase 3 Programs, NDA Review Progress and Licensing Agreements Totaling up to $100 Million in Potential Pre-Commercial Revenue

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NEW YORK, June 15, 2021 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today provided a corporate update on its pipeline with recent and upcoming milestones.

Positive Phase 3 VISION-1 Results

Eyenovia previously announced initial topline data from its Phase 3 VISION-1 clinical trial, which evaluated the company's proprietary pilocarpine solution, administered via the Optejet®, for the treatment of presbyopia. Today, the company is providing additional details from the study. The VISION-1 study evaluated the safety and efficacy of Eyenovia's MicroLine presbyopia microdose formulations versus placebo, all administered via the company's proprietary Optejet delivery Micro-Array Print technology.

Key highlights from the 2% MicroLine dose include:

- A higher proportion of subjects met the primary endpoint of 3-line or greater improvement in near vision with 2% MicroLine as compared to placebo (Odds Ratio=7.7; statistically significant difference $p<0.05$).
- A higher proportion of subjects achieved 2-line or greater improvement in near vision with 2% MicroLine as compared to placebo (Odds Ratio=10.8, statistically significant difference $p<0.05$)
- 71% of patients reported a meaningful improvement in near vision according to an exit survey conducted by study investigators;
- All ocular AEs were trace to mild in severity and transient in nature. Importantly, fewer than 3% of study participants reported headache and brow ache. This compares very favorably to eye drop formulations of pilocarpine, which has been observed in prior studies to cause brow ache or headache in 20% to 25% of study participants;
- Eyenovia plans to present the full data set from VISION-1 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 (MAP™) 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.

To support the submission of a New Drug Application (NDA), the company is on track to initiate a second Phase 3 registrational trial, VISION-2, later this year. VISION-2 will be a double-masked, placebo-controlled, cross-over superiority trial designed to enroll 120 patients randomized between 2% pilocarpine and placebo cohorts. Topline data is anticipated in mid-2022.

It is estimated that as many as 18 million people between the ages of 40-55 suffer from presbyopia in the U.S. alone, suggesting a multi-billion-dollar addressable market for MicroLine, if approved.

MydCombi™ PDUFA Date Set for October 28, 2021

Eyenovia is developing MydCombi for pharmacologic mydriasis, a market that the company estimates to be greater than $250 million annually in the U.S. alone. In March 2021, the U.S. Food and Drug Administration accepted Eyenovia's NDA, which was supported by two successful Phase 3 studies, MIST-1 and MIST-2. FDA has assigned a PDUFA target action date of October 28, 2021.

If approved, Eyenovia anticipates marketing MydCombi with a small, targeted sales force. The company has also partnered with EVERSANA, a leading provider of commercial services to the global life sciences industry, to assist with the launch.

MicroPine Licensing Agreements with Bausch Health and Arctic Vision

Eyenovia previously disclosed two licensing agreements for its investigational treatment for the reduction of pediatric myopia progression, MicroPine (atropine): with Arctic Vision for Greater China and Korea, and Bausch Health for the United States and Canada. Eyenovia has the potential to earn up to $100 million in development milestones over the next four years, as well as significant sales royalties, if approved. Development is progressing as planned. Eyenovia continues to evaluate potential licensing partners covering other key geographical territories.

Bausch Health is in the process of assuming responsibilities for the ongoing conduct of the CHAPERONE trial and enrollment is proceeding as planned during the transition of the program.

Arctic Vision recently announced completion of over $100 million in Series B financing to support the progress of their pipeline, including MicroLine and MicroPine, as well as in-house R&D capabilities, business development, and organizational growth.

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.

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

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 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 (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining 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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