Eyenovia Announces FDA Acceptance of IND for MicroLine for Presbyopia, Clearing Path to Initiate Phase 3 VISION Trial by Year End

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NEW YORK--(BUSINESS WIRE)--Dec. 3, 2020-- Eyenovia, Inc., (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the U. S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for MicroLine, a proprietary pilocarpine formulation for the improvement in near vision in patients with presbyopia. The Company intends to initiate the Phase 3 VISION program, beginning with the VISION-1 study later this month.

Presbyopia, the age-related hardening of the lens causing blurred near vision, affects approximately 113 million Americans. Vision impairment typically begins after age 40 and is often corrected with eyeglasses, contact lenses or surgery. Because many individuals with presbyopia have otherwise normal vision, presbyopia has been shown to have a negative impact on quality of life and wearing glasses is often the first outward sign of aging.

MicroLine is Eyenovia's proprietary presbyopia formulation of pilocarpine. Pilocarpine is a well-characterized drug in ophthalmology, with many studies demonstrating its ability to increase the eye's depth of focus to counter the age-related loss of accommodative effect and improve near vision. The use of pilocarpine for presbyopia as an eye drop may be limited due to the potential for dose-related side effects as well as the inconvenience and inconsistency of dosing with traditional eye droppers. Eyenovia's MicroLine is a proprietary microdosed formulation of pilocarpine that is delivered via the Company's Optejet® dispenser. High precision microdosing at approximately 1/5 th the drug volume of a traditional eye dropper with the Optejet is designed to deliver targeted, consistent doses more conveniently than typical eyedroppers.

"We prioritized the development of MicroLine because of the significant unmet need we see in presbyopia, and because we believe MicroLine can address many shortcomings of current treatment options by delivering a microdose of pilocarpine via our proprietary Optejet dispenser," said Dr. Sean Ianchulev, Chief Executive officer and Chief Medical Officer of Eyenovia. "We are on track to initiate the VISION-1 Phase 3 trial by year end, subject to any impacts of COVID-19. We believe the VISION studies could confirm that our approach to presbyopia is a well-tolerated, effective, on-demand complement to reading glasses for those situations when wearing glasses is less than ideal."

The VISION trials are Phase 3, doubled-masked, placebo-controlled, cross-over superiority trials that will enroll participants between the ages of 40 and 60 with presbyopia. The primary endpoint is binocular distance corrected near visual acuity. MicroLine is intended for the "on demand" symptomatic treatment of near vision impairment secondary to presbyopia.

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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Eyenovia Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer

jgandolfo@eyenovia.com

Eyenovia Investor Contact:
Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
(646) 751-4363

Eyenovia Media Contact:
Diana Soltesz
Pazanga Health Communications
dsoltesz@pazangahealth.com
(818) 618-5634

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