Eyenovia Announces Publication of MIST Pivotal Studies Demonstrating the Efficacy and Safety of its MAP™ Fixed-Combination Tropicamide-Phenylephrine Product for Mydriasis

March 17, 2021

NEW YORK--(BUSINESS WIRE)--Mar. 17, 2021-- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced the publication of "Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST: pooled randomized Phase III trials" in *Therapeutic Delivery.*

The publication features pooled results from two prospective, double-masked, controlled, cross-over superiority Phase 3 studies that concluded a micro-dosed fixed-combination of tropicamide 1% and phenylephrine 2.5% for pupil dilation (mydriasis) is safe and effective and produced clinically relevant and statistically superior pupil dilation compared with either agent alone and placebo.

Approximately 93% of eyes treated with tropicamide-phenylephrine achieved 6 mm or greater dilation at 35 minutes post-dose as compared to 78% with tropicamide and 2% with phenylephrine. Additionally, the proportion of fully non-responsive pupils at 35 minutes post-dose was 98% with tropicamide-phenylephrine compared with 76% and 5%, respectively, with tropicamide and phenylephrine alone. Adverse events with tropicamide-phenylephrine were infrequent at 3% and mild with fewer than 1% of patients reporting blurred vision, reduced acuity, photophobia or instillation site pain. The pooled analysis included 131 subjects and all treatment arms used Eyenovia's proprietary Optejet®, a first-of-its-kind dispenser designed for high precision targeted administration, delivering approximately 80% less medication and preservatives to patients than eyedroppers and potentially improving local tolerability.

"Pupil dilation has a deserved reputation for being a cumbersome, time consuming and often uncomfortable part of eye exams, which is why many patients dislike and sometimes forego it," said David Wirta, M.D., Medical Director of the Eye Research Foundation in Newport Beach, Calif., and investigator of a MIST study. "The advent of a combination agent for pupil dilation that can bring patients greater clinical benefits than existing medicines and delivers medication in a novel, less taxing way has the potential to improve our nation's eye health, hopefully moving more people to have a comprehensive eye exam."

This publication follows the U.S. Food and Drug Administration's recent acceptance of Eyenovia's New Drug Application (NDA) for MydCombi™, the micro-dosed fixed-combination tropicamide-phenylephrine agent evaluated in these pivotal studies. The expected PDUFA date for the potential approval of MydCombi is in the fourth quarter of 2021.

"This publication further validates that microdosed tropicamide-phenylephrine with our proprietary and novel Optejet dispenser has many advantages that could make pupil dilation easier, more comfortable and safer. The Optejet may reduce the risk of cross-contamination because unlike an eyedropper bottle, the Optejet has no protruding parts. The MAP drug delivery may also enable anesthetic-free dilation and streamlines care, making the process more efficient," said Beth Scott, OD, Team Leader and Head of Medical Affairs at Eyenovia. "These results highlight the potential advantages of our Optejet dispenser to effectively and safely deliver advanced therapies, with the ability to be applied to additional medications and indications."

MydCombi was developed to address several challenges eye care practitioners and their patients face related to pupil dilation, a procedure conducted during most of the estimated 80 million office-based comprehensive and diabetic eye exams performed in the U.S. annually. The current standard of care for pupil dilation requires multiple eye drops including a topical anesthetic, given at least several minutes apart, which can take considerable time and often cause both discomfort and drug overflow. The design of eyedroppers also lends itself to the possibility of inadvertent contact with the eye itself, which may be an issue, as the same eyedropper bottle is often shared among a number of patients. In contrast, MydCombi is delivered by Eyenovia's proprietary Optejet dispenser, designed to ensure consistent and easy application of two mydriatic medications in a quick, touchless micro-mist application. The product is designed with no protruding parts, which may help prevent accidental touching of the ocular surface.

"Dilating the pupil is a challenging, albeit critical part of any comprehensive eye exam, providing eye care professionals with the necessary clarity and visibility to fully examine the eye," said Thomas R. Walters, M.D., president of Texan Eye P.A. and Medical Director of Eye LASIK Austin. "The prospect of an improved pupil dilation regimen, especially one that makes dilation in children easier and more comfortable, has the potential to elevate the level of routine care providers offer their patients."

"Clinicians and eye care professionals have long been ready for options beyond eye drops, which by design, often expose patients to higher-than-needed doses of medication and prolong eye exams," said William J Flynn MD, Clinical Professor of Ophthalmology University of Texas Health, San Antonio. "The combination of a more effective mix of medicines and a cleaner, comfortable, more targeted delivery system like Eyenovia's Optejet, could make pupil dilation more palatable for patients and practices more efficient."

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 and follow us on LinkedIn and Twitter.

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: the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; 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 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 certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for certain of 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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Source: Eyenovia, Inc.