



## **Eyenovia Submits New Drug Application to FDA for Pharmacologic Mydriasis with MydCombi Targeting 80 Million Patient Encounters in the U.S. Annually**

December 29, 2020

NEW YORK--(BUSINESS WIRE)--Dec. 29, 2020-- [Eyenovia, Inc.](#) (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company with Phase 3 programs in presbyopia, myopia and mydriasis, today announced that it has submitted a New Drug Application (NDA) to the U. S. Food and Drug Administration (FDA) for MydCombi™, a unique fixed combination mydriatic (pupil dilation) agent. If approved, MydCombi would be the first microdosed ocular therapeutic with a high precision smart delivery system.

The NDA submission follows the initial enrollment of the VISION-1 study, Eyenovias Phase 3 study for MicroLine in presbyopia, with top-line data expected the first half of 2021.

MydCombi was developed to address several needs of the eye care practitioner's office. Pupil dilation is 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 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 Eyenovias proprietary Optejet® dispenser, designed to ensure consistent and easy application of two mydriatic medications in a quick, touchless micro-mist application. The product is also designed with no protruding parts, which may help prevent accidental touching of the ocular surface.

"The NDA application for MydCombi represents a milestone for Eyenovias. It is the first of our three late-stage programs to complete Phase 3 studies leading to this FDA submission, which not only validates our platform technology, but also demonstrates the passion and tireless efforts of all Eyenovians. If approved, MydCombi could be available late next year or early 2022 and improve a common clinical practice that has not advanced in nearly a century," said Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovias. "MydCombi, delivered by our proprietary Optejet touchless dispenser, may have several advantages over the current standard of care for in-office mydriasis that are especially important in today's environment. With no protruding parts and recessed nozzle and shutter, Optejets design enables touch-free mydriasis and helps reduce the risk of cross contamination."

The NDA submission was based on the MIST-1 and MIST-2 studies. In these two Phase 3 studies, a fixed combination of micro-dosed phenylephrine 2.5% and tropicamide 1% ophthalmic solution was shown to be safe and effective for pharmacologic mydriasis. Approximately 94% of treated eyes achieved 6mm or greater dilation at 35 minutes post-instillation. All adverse events were infrequent at 3.1%; fewer than 1% of patients reported blurred vision, reduced acuity, photophobia or instillation site pain.

"Pupil dilation is a necessity for most eye exams. The process today can add several minutes to each exam, which over the course of the day often translates to fewer patients examined. MydCombi has the potential to significantly improve patient flow and make the in-office mydriasis process more efficient and more comfortable for patients," said Dr. James Tsai, president of New York Eye and Ear Infirmary of Mount Sinai and a member of the Eyenovias Scientific Advisory Board.

### **About Eyenovias, Inc.**

Eyenovias, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovias is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more Information, visit [www.eyenovias.com](http://www.eyenovias.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: 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, Eyenovias 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](mailto:jgandolfo@eyenovia.com)

**Eyenovia Investor Contact:**

Eric Ribner  
LifeSci Advisors, LLC  
[eric@lifesciadvisors.com](mailto:eric@lifesciadvisors.com)  
(646) 751-4363

**Eyenovia Media Contact:**

Diana Soltesz  
Pazanga Health Communications  
[dsoltesz@pazangahealth.com](mailto:dsoltesz@pazangahealth.com)  
(818) 618-5634

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