Eyenovia Announces FDA Approval of Redwood City as Commercial Manufacturing Facility

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Redwood City, California to complement Eyenovia's facility in Reno, Nevada as well as its contract manufacturer, Coastline International, to produce commercial supply of Mydcombi

NEW YORK, Feb. 13, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company, today announced that the company's facility in Redwood City, California successfully completed FDA inspection for approval as a commercial manufacturing facility. The Redwood City facility will primarily be used for final assembly, packaging and labeling activities in support of Mydcombi, the first and only fixed combination of tropicamide and phenylephrine for in-office and pre-surgical pupil dilation utilizing Optejet™ technology.

Redwood City complements Eyenovia's manufacturing capabilities in Reno, as well as its contract manufacturer, Coastline International, to produce commercial supply of Mydcombi in the Company's proprietary Optejet dispensing platform.

"The FDA inspection of our Redwood City facility was completed efficiently and with no significant concerns raised on the part of the inspector, clearing the way for us to perform final assembly, packaging and labeling in support of a broader U.S. launch of Mydcombi," stated Michael Rowe, Eyenovia's Chief Executive Officer. "With Redwood City and Reno now online and operational, we have the capacity to manufacture both commercial product as well as clinical supply in support of our ongoing CHAPERONE clinical trial for pediatric progressive myopia as well as initial testing of other product candidates that leverage our Optejet technology."

"I am very pleased with the results of the audit and commend our manufacturing, engineering, quality and regulatory staff for their diligence and work to make this a reality," added Bren Kern, Chief Operating Officer. "The team had been working tirelessly in preparation for this key milestone and their efforts bore out in the result."

PLEASE GO TO MYDCOMBI.COM FOR IMPORTANT SAFETY INFORMATION for MYDCOMBI ™(tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis.

In addition to commercializing Mydcombi, in August 2023, Eyenovia acquired the U.S. commercial rights to APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) from Formosa Pharmaceuticals. APP13007, which is currently under review by the FDA, is a potent steroid being developed to reduce pain and inflammation following ocular surgery. The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia and myopia progression (partnered with Arctic Vision in China and South Korea).

For more information, visit 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 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, and the potential for approval of APP13007. 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, 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 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, legislative and geopolitical 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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