Eyenovia Announces Commencement of Manufacturing of its Advanced, Second Generation Optejet Device

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The Gen-2 Optejet is designed for an optimized user experience while ensuring extended patent protection for products using the platform through 2041

NEW YORK, Oct. 01, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company, today announced that the Company has commenced manufacturing of registration batches of its FDA-approved mydriasis product, Mydcombi, a key step in the approval process for its state-of-the-art Gen-2 Optejet dispensing platform.

Mydcombi will undergo 12-month stability testing and other functional testing in the Gen-2 Optejet device that is consistent with feedback from the Type-C meeting on Eyenovia's device qualification plan that the Company received from the FDA in July.

"We were very pleased to have received feedback from the FDA that was very consistent with our Gen-2 qualification plan, allowing us to move forward with manufacturing and testing as quickly and efficiently as possible," stated Michael Rowe, Chief Executive Officer of Eyenovia. "With advances from the prior generation product, including one-button use and compatibility with our digital compliance monitoring program, Optecare™, we view the introduction of the Gen-2 Optejet as a significant upcoming inflection point for our company."

"Importantly, the work that we are doing for Mydcombi in the Gen-2 Optejet device may also provide significantly lower manufacturing costs and streamline future regulatory interactions as we expand the Gen-2 platform to additional therapeutics, both within our own pipeline as well as those in development partnerships, such as dry eye," Mr. Rowe concluded.

Eyenovia anticipates completion of testing of its Mydcombi registration batches by the end of next year, with a potential SNDA filing in early 2026.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic technology company developing a pipeline of advanced products based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi® for mydriasis, clobetasol propionate ophthalmic suspension, 0.05% for post-surgical pain and inflammation, as well as the ongoing late-stage development of medications in the Optejet device for pediatric progressive myopia as well as out-licensing for additional indications. For more information, visit Eyenovia.com.

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

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

PLEASE GO TO CLOBETASOLBID.COM FOR IMPORTANT SAFETY INFORMATION for Clobetasol Propionate Ophthalmic Suspension 0.05%

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, the impact of the Gen-2 Optejet device, and the timing for availability and sales growth of our approved products. 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 products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and 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 product candidates; 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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