



Eyenovia Congratulates Formosa Pharmaceuticals on FDA Approval of Clobetasol Propionate Ophthalmic Suspension 0.05% for the Treatment of Post-operative Inflammation and Pain Following Ocular Surgery

March 5, 2024 at 8:00 AM EST

Approval based on nearly 9 out of 10 patients achieving complete absence of post-surgical pain and 6 out of 10 achieving total absence of inflammation within 15 days post-ocular surgery

Eyenovia plans to launch in the U.S. as soon as this summer using its Mydcombi™ sales force providing pre-surgical pupil dilation and post-surgical care in an estimated \$1.3 billion annual U.S. market

NEW YORK, March 05, 2024 (GLOBE NEWSWIRE) -- [Eyenovia, Inc.](#) (NASDAQ: EYEN), a commercial-stage ophthalmic company, today congratulates Formosa Pharmaceuticals (TWO:6838) on the FDA approval of clobetasol propionate ophthalmic suspension 0.05% for the treatment of post-operative inflammation and pain following ocular surgery. Eyenovia acquired the U.S. commercial rights to clobetasol propionate ophthalmic suspension 0.05% from Formosa Pharmaceuticals in August 2023.

Formosa's proprietary APNT™ technology, which has been used in the development of clobetasol propionate ophthalmic suspension to reduce the particle size of the active pharmaceutical ingredient, is thought to provide many benefits, including high uniformity and purity, improved stability, improved dispersion properties and greater bioavailability.

"We congratulate Formosa Pharmaceuticals on the FDA approval of clobetasol propionate ophthalmic suspension 0.05%, the first approved therapeutic to leverage its APNT™ formulation platform, and the first new ophthalmic steroid to enter the U.S. market in over 15 years," stated Michael Rowe, Eyenovia's Chief Executive Officer. "The efficacy profile of clobetasol propionate ophthalmic suspension 0.05% is highly desirable, and adverse events were seen in no more than 2% of patients; many of the adverse events may have been caused by the surgical procedure itself. Moreover, we believe its efficacy, safety, and convenient dosing regimen – twice daily without titration versus up to four times daily for other post-surgical topical ophthalmic treatment options – will resonate with patients and eye doctors alike for the almost 7 million ocular surgeries that take place in this country every year."

"In addition to its many favorable clinical attributes, clobetasol propionate ophthalmic suspension 0.05% fits perfectly within our commercial strategy by allowing us to leverage our sales and distribution infrastructure. We are working towards a robust launch mid-year starting with an educational campaign focused on cataract surgeons," Mr. Rowe concluded.

Longer term, Eyenovia is exploring further development of the product in the Optejet dispenser as a potential treatment for dry eye, which the Company estimates to be a \$3.6 billion market.

Eyenovia will provide a further update on this and other recent developments, including timing for approval of its tradename for this product, during its fourth quarter and full-year 2023 results conference call in mid-March.

PLEASE GO TO [CLOBETASOL.BID.COM](#) FOR IMPORTANT SAFETY INFORMATION for CLOBETASOL PROPRIONATE OPHTHALMIC SUSPENSION 0.05%

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, as well as clobetasol propionate ophthalmic suspension 0.05% to reduce pain and inflammation following ocular surgery, which was approved by the FDA on March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia (Apersure) and myopia progression (MicroPine, 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 products, product candidates and platform technology, and the timing for launch of clobetasol propionate ophthalmic suspension 0.05% and any additional indications for its use. 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 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.

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:

Eyenovia, Inc.
Norbert Lowe
Vice President, Commercial Operations
nlowe@eyenovia.com



Source: Eyenovia, Inc.