Eyenovia and Formosa Pharmaceuticals Initiate Co-Development of Clobetasol Propionate Ophthalmic Suspension (0.05%) for the Treatment of Acute Dry Eye Disease in the U.S.

August 7, 2024 at 5:11 PM EDT

Product-candidate would incorporate new steroid with the Optejet® for the millions of dry eye patients who experience periodic flare-ups

NEW YORK, Aug. 07, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in pediatric progressive myopia, today announced that it has signed a non-binding agreement with Taiwan-based Formosa Pharmaceuticals (TWO:6838) whereby the companies will co-develop a formulation of clobetasol propionate ophthalmic suspension 0.05% ("clobetasol propionate") in combination with the Optejet device for the short-term relief of dry eye disease.

Both companies will conduct due diligence and work to execute a definitive agreement that will include the sharing of development costs and the division of profits upon commercialization. This agreement will effectively expand the existing collaboration agreement between the companies, which was signed in February 2023, which included the testing of clobetasol propionate in the Optejet and plans for a consultation meeting with the FDA to discuss dry eye indications.

Clobetasol propionate is a potent steroid that was approved by the FDA on March 4, 2024, for the reduction of inflammation and pain associated with the estimated seven million ocular surgeries performed in the U.S. annually. Currently, the U.S. market for topical ocular steroids and steroid combinations totals approximately $1.3 billion in sales. This additional acute dry eye indication could expand the use of clobetasol by the millions of people who experience flare-ups in their disease despite their existing treatments.

"Clobetasol propionate has a unique profile that lends itself to exploring for use in dry eye," said Michael Rowe, Chief Executive Officer of Eyenovia. "The drug's efficacy in pain and inflammation relief as well as its low incidence of adverse events could one day be a boon to the millions of dry eye patients who suffer from periodic flare-ups of the disease. The Eyenovia team looks forward to working with our partners at Formosa to move this project forward with our Optejet dispenser technology."

Erick Co, President & Chief Executive Officer of Formosa Pharma, said, "Formosa Pharma is eager to take the next step in the evolution of our partnership with Eyenovia. We have already proven our respective technologies to be compatible, and successfully developing APNT® formulations for advanced delivery devices such as the Optejet represents a tremendous opportunity for both companies."

Clobetasol propionate ophthalmic suspension 0.05% is the first product developed using Formosa's proprietary APNT® nanoparticle formulation platform. Formosa's APNT® platform reduces an active pharmaceutical ingredient's particle size with high uniformity and purity, thereby allowing penetration to relevant compartments in the eye, and ultimately enhancing bioavailability.

PLEASE GO TO CLOBETASOLBID.COM for IMPORTANT SAFETY INFORMATION for clobetasol propionate ophthalmic suspension 0.05%

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic technology company commercializing Mydcombi™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% for mydriasis, clobetasol propionate ophthalmic suspension, 0.05% for postsurgical inflammation and pain, and developing the Optejet® device for use both in connection with its own drug-device therapeutic product 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.

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. 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.

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.