Eyenovia Announces Taiwan Export License Approval to Commence Shipment of Clobetasol Propionate Ophthalmic Suspension (0.05%) to the U.S.

September 5, 2024 at 7:00 AM EDT

Eyenovia is planning for a U.S. launch for Clobetasol in late September 2024

NEW YORK, Sept. 05, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in development for the treatment of pediatric progressive myopia, today announced that its strategic partner, Taiwan-based Formosa Pharmaceuticals (TWO:6838), was granted a Taiwan Export License for clobetasol propionate ophthalmic suspension 0.05% ("clobetasol propionate") to allow for shipment of commercial product to the U.S.

Clobetasol is a powerful steroid approved for reducing inflammation and pain following the approximately seven million ocular surgeries performed annually in the U.S. In August 2023, Eyenovia secured exclusive rights to distribute and sell clobetasol in the U.S., entering a market for topical ocular steroids and steroid combinations valued at approximately $1.3 billion annually.

"Clobetasol is the first new ophthalmic steroid to be approved in the U.S. in over 15 years, with benefits that may position it as a leading choice for postsurgical care," said Dr. Francis S. Mah, Director of the Cornea Service at Scripps Clinic in La Jolla, California and member of the Eyenovia Scientific Advisory Board. "Clinical studies have shown that 80% of patients experienced rapid, complete relief from postsurgical pain within four days of the procedure, and 60% achieved total resolution of inflammation within 15 days after surgery. From a safety perspective, fewer than 1% of patients experienced an increase in eye pressure, a side effect of concern to ocular surgeons and commonly associated with steroids."

A recent survey of 100 ophthalmic surgeons highlighted efficacy and cost as the two most important factors when choosing a treatment for postoperative inflammation and pain. Clobetasol's proven efficacy, allowing for just twice-daily dosing, offers an easier regimen versus other treatments that require up to four doses per day plus titration. Additionally, Clobetasol will be competitively priced to enhance affordability for all patients, regardless of their insurance coverage.

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. At Eyenovia, our vision is to improve yours. 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.
Andrew Jones
Chief Financial Officer
ajones@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.