Eyenovia Acquires U.S. Commercial Rights to APP13007 (Clobetasol Propionate Ophthalmic Nanosuspension, 0.05%) from Formosa Pharmaceuticals

August 16, 2023 at 6:00 AM EDT

APP13007, if approved, may have an advantageous profile in dosing frequency and side effects while reducing the inflammation and pain associated with ocular surgery

Further leverages Eyenovia's Mydcombi sales force and represents additional near-term potential revenue source

Eyenovia plans to evaluate novel clobetasol formulations in its proprietary Optejet® dispensing platform as a potential treatment for dry eye, estimated to be a $3.6 billion market in the U.S.

NEW YORK, Aug. 16, 2023 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company commercializing Mydcombi™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% for mydriasis and developing the Optejet® device for use both in connection with its own drug-device therapeutic product candidates for presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced that it has entered into an agreement with Taiwan-based Formosa Pharmaceuticals (TWO:6838) whereby Eyenovia has acquired the exclusive U.S. rights to distribute and sell APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%), which is currently under review by the U.S. Food and Drug Administration (FDA). The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Per the terms of the agreement, Eyenovia will make single-digit million-dollar payments to Formosa in cash and shares of Eyenovia common stock upon the signing of the agreement, upon FDA approval of APP13007 and the transfer of the NDA to Eyenovia, and following the first commercial sale of APP13007. Additionally, Formosa will be eligible for payments related to the attainment of sales milestones by Eyenovia.

Clobetasol is a potent steroid not yet available in ophthalmology that, if approved, may have an advantageous profile in dosing frequency (2x/day versus 4x/day for most other post-surgical eye drops) and tolerability while reducing the inflammation and pain associated with ocular surgery. It is estimated that there are more than seven million ocular surgeries in the U.S. each year with topical ocular steroids and steroid combinations currently totaling $1.3 billion in sales.

"We are pleased to have entered into this agreement with our development partner, Formosa Pharmaceuticals, to acquire the U.S. commercial rights to APP13007. If approved, APP13007 would be an attractive new treatment option for the aftereffects of ocular surgery, most notably inflammation and pain," stated Michael Rowe, chief executive officer of Eyenovia. "The acquisition of APP13007 is an opportunistic addition to our product portfolio, and a new potential source of near-term revenue, at what we believe are very favorable terms for both parties. Alongside our mydriasis product, Mydcombi, we can bring additional value to ophthalmic surgeons and their patients through the use of MydCombi for pre-operative dilation and APP13007 post-operatively, both supported by a single dedicated sales force."

"We will also be discussing with the FDA the opportunity to develop novel clobetasol formulations as a late-stage asset for use with the Optejet as a potential treatment for dry eye, a market estimated to be worth over $3.6 billion. This agreement ushers in an exciting new chapter in Eyenovia's emergence as a commercial ophthalmic company," Mr. Rowe concluded.

"Formosa Pharma enters this partnership with Eyenovia with great enthusiasm. The complementarity of each company's products, as well as corporate strategies, lay the foundation for a long-term and rewarding alliance for all stakeholders," said Erick Co, President and CEO of Formosa Pharmaceuticals. "With Eyenovia's bold and creative marketing strategies, we are confident that APP13007 will realize its potential in providing a formidable choice for ophthalmologists and patients for the relief of inflammation and pain following ocular surgery."

"Given my focus on new ophthalmic technologies, having worked on the clinical development of both Eyenovia's Mydcombi and Formosa's clobetasol ophthalmic nanosuspension, I can speak directly to the significant advancements that each represents in its respective indication," stated William J. Flynn, M.D., Research Director of R & R Eye Research in San Antonio. "I look forward to the potential of prescribing APP13007 in the first half of next year and intend to incorporate it and Mydcombi into my practice as soon as possible."

APP13007 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 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. Eyenovia is currently focused on the commercialization of Mydcombi for mydriasis, as well as the ongoing late-stage development of medications in the Optejet device for presbyopia and myopia progression. 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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