Eyenovia Announces FDA Approval of Coastline International as Contract Manufacturer to Initiate Mydcombi Commercial Production

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Anticipates having product available to ship in January 2024

NEW YORK, Nov. 02, 2023 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company commercializing Mydcombi™ for mydriasis, preparing for regulatory approval of APP13007 for relief of pain and inflammation post ocular surgery, and incorporating its advanced 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 the FDA has approved Eyenovia's Supplemental New Drug Application (sNDA), adding Coastline International as a contract manufacturer. Coastline will manufacture cartridge subassemblies for Mydcombi, the only FDA-approved tropicamide and phenylephrine hydrochloride fixed combination for mydriasis (office-based pupil dilation).

"One of the many benefits of Mydcombi is that, unlike eye droppers, there is no protruding tip that can come in contact with the patient's eye. In many applications today, eyecare institutions and surgeons are discarding bottles after each use to prevent this risk of cross-contamination, creating waste and unnecessary expense," stated Michael Rowe, chief executive officer of Eyenovia. "We believe Mydcombi, because of its design, addresses this challenge and can provide significant cost savings to doctors and surgical centers. With FDA approval of Coastline, our manufacturing capabilities are in place, and we anticipate initiating Mydcombi commercial production imminently with the goal of having product available to ship in January of 2024."

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.

In addition to commercializing Mydcombi, in August 2023, Eyenovia acquired the U.S. commercial rights to APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) from Formosa Pharmaceuticals. APP13007, which is currently under review by the FDA, is a potent steroid being developed to reduce pain and inflammation with twice-a-day dosing following ocular surgery. The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia and myopia progression (partnered with Bausch+Lomb in the U.S. and Canada and 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.

Indication
MYDCOMBI (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired.
IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS: Known hypersensitivity to any component of the formulation
WARNINGS AND PRECAUTIONS
FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION
This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered.
Mydriatics may produce a transient elevation of intraocular pressure.
Significant elevations in blood pressure have been reported. Caution in patients with elevated blood pressure.
Rebound miosis has been reported one day after installation.
Remove contact lenses before using.
DRUG INTERACTIONS
Atropine-like Drugs: May exaggerate the adrenergic pressor response
Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors
Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents
ADVERSE REACTIONS
Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics
Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide
To report SUSPECTED ADVERSE REACTIONS, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)
See www.mydcombi.com for **FULL PRESCRIBING INFORMATION**

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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