Eyenovia Announces First Commercial Sale of Mydcombi™

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Represents the first FDA approved and commercially available fixed combination of tropicamide and phenylephrine for pupil dilation

Validates Eyenovia's proprietary Optejet ® dispensing platform

World-renowned board-certified ophthalmologist Dr. Nathan M. Radcliffe becomes first to incorporate Mydcombi into his daily practice

NEW YORK, Aug. 03, 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 the first commercial sale of Mydcombi. Mydcombi was approved by the US Food and Drug Administration on May 8, 2023. The initial sale was to world-renowned board-certified ophthalmologist Dr. Nathan M. Radcliffe, who has become the first physician in the U.S. to incorporate Mydcombi into his daily practice.

"We are very pleased to initiate sales of Mydcombi to select professional offices so that ophthalmologists, optometrists, technicians and their patients can experience the benefits of Mydcombi's metered spray delivery relative to conventional multiple eye drops," stated Michael Rowe, chief executive officer of Eyenovia. "We have now kicked off our targeted launch while we continue to ramp up our internal manufacturing capabilities."

"I have been eagerly awaiting the commercial availability of Mydcombi to provide a great experience to my patients who require pupil dilation," stated Dr. Radcliffe. "In addition, given the potential for streamlining patient throughput that Mydcombi may facilitate, I anticipate that it will be the go-to mydriasis agent in my own practice going forward."

Mydcombi is designed to streamline the estimated 106 million office-based comprehensive eye exams with pupil dilation performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for ocular surgery. In clinical studies, Mydcombi was statistically superior to tropicamide and to phenylephrine administered alone, with effective pupil dilation in almost two thirds of patients seen as early as 20 minutes after application, with excellent tolerability. The product should not be used in patients with known hypersensitivity to any component of the formulation.

IMPORTANT SAFETY INFORMATION for MYDCOMBI ™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

INDICATIONS

MYDCOMBI is indicated to induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired

CONTRAINDICATIONS: In patients with 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)

Please go to www.mydcombi.com for **FULL PRESCRIBING INFORMATION**

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 presentation 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.

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