Eyenovia Re-Acquires Development and Commercialization Rights to MicroPine in the U.S. and Canada

January 16, 2024 at 7:00 AM EST

MicroPine, currently in late phase III for pediatric progressive myopia, to complement Eyenovia's commercial-stage asset, Mydcombi, as well as its pre-PDUFA candidate, APP13007

Part of corporate strategy to expedite commercialization of advanced products using the Optejet device

Market estimated to be nearly $2 billion annually in the U.S. by Review of Myopia Management

NEW YORK, Jan. 16, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage, ophthalmic company, today announced that it has re-acquired the rights to MicroPine in the U.S. and Canada.

MicroPine, an investigational eight microliter ophthalmic spray of atropine delivered by Eyenovia's proprietary Optejet device, is being evaluated as a potential treatment for pediatric progressive myopia (worsening near-sightedness), which is characterized by elongation of the sclera/retina. Eyenovia estimates that more than 25 million children in the U.S. suffer from myopia, and, of these, five million are believed to be at high risk for progressive myopia. If left untreated, progressive myopia can ultimately lead to significant vision loss and potential blindness. Prior studies have demonstrated that atropine can slow myopia progression by as much as 60%, and there is a significant unmet need for safe and effective FDA-approved treatment options.

The re-acquisition of MicroPine greatly expands Eyenovia's phase III pipeline and commercial opportunities, as follows:

- As Eyenovia accelerates its commercial capabilities in 2024 with the expanded launch of MydCombi and the anticipated introduction of APP-13007 (pending FDA approval anticipated in March), MicroPine adds a major late-stage asset in a large market with high unmet medical need;
- Based upon the Company's internal forecast, by acquiring back the MicroPine rights, the overall asset value of the MicroPine program to Eyenovia more than doubles compared to what the Company would have been eligible to receive under the original license agreement;
- Eyenovia will work to accelerate the ongoing CHAPERONE phase III trial and engage with FDA to explore options to expedite development and registration of MicroPine;
- Expands the territories in which the CHAPERONE study may be conducted to support registration as well as the field of potential collaborators to engage for future partnering or strategic discussions.

"With the FDA approval of MydCombi for in-office mydriasis (pupil dilation), together with our recent announcement that we in-licensed the U.S. commercial rights to APP13007 for post-ocular surgical pain and inflammation from Formosa Pharmaceuticals, our commercialization strategy is accelerating," stated Michael Rowe, chief executive officer of Eyenovia. "We believe the addition of MicroPine, if approved, would be highly complementary to these products."

"MicroPine would also utilize our Optejet dispensing technology, which is highly differentiated and confers significant advantages to eye doctors and patients as compared to traditional eye drops, including less systemic exposure, better compliance among children, ease of use, and potentially better local tolerability. Our re-acquisition of the rights to MicroPine in the U.S. and Canada is consistent with our broader corporate strategy to expedite commercialization of advanced products using the Optejet.

"We believe we are ideally positioned to complete remaining development steps in an expedited and capital efficient manner, and, to that end, we plan to meet with the FDA early this year to align on a path forward for this high-value program," Mr. Rowe concluded.

In connection with this transaction, Eyenovia will pay Bausch + Lomb Ireland Limited an upfront payment consisting of $2 million in cash and $3 million in shares of common stock, as well as a low single-digit royalty on Eyenovia's net sales of MicroPine in the United States and Canada.

This agreement has no impact on Eyenovia's ongoing partnership with Arctic Vision, which covers development of MicroPine (as well as Mydcombi and MicroLine/Apersure) for Greater China and South Korea.

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 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 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 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.

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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