Eyenovia Advances MicroLine for the Treatment of Presbyopia Towards Phase III Development and Reprioritizes Late-Stage Ophthalmology Pipeline

October 29, 2019

Defers development activities of MicroProst and MicroTears

Company to host conference call on Tuesday, October 29, 2019 at 5:00 pm ET

NEW YORK, Oct. 29, 2019 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology, today announced that the Company is advancing the development of its MicroLine program for the improvement in near vision in patients with presbyopia towards Phase III development. As a result of prioritizing MicroLine in tandem with its MicroPine (progressive myopia) and MicroStat (mydriasis) programs, the Company is deferring development activities for its MicroProst (glaucoma and ocular hypertension) and MicroTears (red eye and itch relief/lubrication) programs.

Presbyopia is a non-preventable, age-related hardening of the lens, which causes the gradual loss of the eye's ability to focus on nearby objects, commonly known as farsightedness. There are currently no known FDA-approved drugs for the improvement in near vision in patients with presbyopia and existing modalities are typically device-based, such as reading glasses or contact lenses. In the United States, presbyopia affects an estimated 113 million people, of which Eyenovia estimates that approximately 43 million people between the ages of 40 and 65 who have otherwise normal vision could benefit from a pharmacologic treatment option like MicroLine.

"The MicroLine program, based on our proprietary piezo-formulation of the well-known drug pilocarpine, could potentially be one of the first pharmacologic treatment options for presbyopia. Combined with our novel platform technology, we believe that Eyenovia can provide people interested in enhancing their lifestyle with pharmacotherapy similar to other aesthetic-focused products. MicroLine is designed to replace reading glasses for approximately 3-4 hours, while addressing the tolerability and instillation issues associated with traditional eye drop approaches," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "We anticipate initiating and completing the Phase III VISION trials for MicroLine in 2020."

Dr. Fred Eshelman, Eyenovia's Chairman of the Board added, "After conducting a strategic review of Eyenovia's pipeline with the goal of maximizing the value of its portfolio, we believe that MicroLine, MicroPine and MicroStat represent the highest value opportunities for Eyenovia, with potential product launches from 2022 to 2024. We believe these three programs focus on areas with significant unmet needs or where the patient experience could be greatly improved. MicroLine, in particular, represents an exciting part of our pipeline, potentially enabling millions of people in the United States to forgo their reading glasses for approximately 3-4 hours of improved vision."

The Company expects the reprioritization of its programs to yield overall cost savings to Eyenovia of approximately $1.5 to $1.9 million in 2020.

Program	Indication	2020 Milestones	Estimated U.S. Market Opportunity
Micro**Line**	Presbyopia	Initiate and Complete Phase III VISION Study	$2B+
Micro**Pine**	Progressive Myopia	Complete Phase III CHAPERONE Enrollment	$5B+
Micro**Stat**	Mydriasis	File NDA	$300M+

Conference Call and Webcast

The conference call is scheduled to begin at 5:00 pm ET on Tuesday, October 29, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 3192808. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenovia.com.

After the live webcast, the event will be archived on Eyenovia's website for one year. In addition, a telephonic replay of the call will be available until November 5, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 3192808.

About Eyenovia

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more Information please visit www.eyenovia.com.

About MicroLine for Presbyopia

MicroLine is Eyenovia's pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Eyenovia believes that its high precision microdosing technology combined with the well-known drug pilocarpine could provide short-term improvement in vision in patients, lasting approximately 3-4 hours while addressing tolerability and instillation issues associated with macrodose pilocarpine.

Upcoming Milestone: Initiate and Complete MicroLine Phase III Trial in 2020

About MicroPine for Progressive Myopia
MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. Progressive myopia is estimated to affect close to 5 million people in the United States who suffer from uncontrolled axial elongation of the sclera leading to increasing levels of myopia and in some cases major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. Early dose finding studies by collaborative academic groups have demonstrated high therapeutic potential with low dose atropine which can reduce myopia progression by 60 – 70% with a sustained effect through three years. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology indicates Level 1 (highest) evidence of efficacy for the role of low dose atropine for progressive myopia (Ophthalmology 2017;124:1857-1866; Ophthalmology 2016; 123(2) 391:399).

Feasibility Dose-finding Atropine Studies: ATOM 1; ATOM 2; LAMP (Independent Collaborative Group Trials)
Upcoming Milestone: Complete Enrollment of the Phase III CHAPERONE Study in 2020

About MicroStat for Mydriasis
MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (phenylephrine 2.5% -tropicamide 1%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to address the growing needs of the estimated 80 million office-based comprehensive and diabetic eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. We are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Upcoming Milestone: File NDA in 2020

About Optejet™ and MicroRx Ocular Therapeutics
Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 µL of drug, consistent with the capacity of the tear film of the eye. We believe the volume of ophthalmic solution administered with the Optejet is less than 75% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink reflex. Successful use of the Optejet has been demonstrated with minimal training in 85% of topical medication administrations compared to 40 – 50% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

Forward Looking Statements
Except for historical information, all of 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 in the United States for our product candidates. 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 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 SEC. In addition, such statements could be affected by risks and uncertainties related to, among other things: the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our ability to identify new product candidates; 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; the potential advantages of our product candidates; risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our ability to timely develop and implement manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; fluctuations in our financial results; our ability to raise money; intellectual property risks; changes in legal, regulatory and legislative 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, we do not undertake any obligation to update any forward-looking statements.

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