Eyenovia Announces Presentation of Successful Phase 3 Studies at the ASCRS-ASOA Annual Meeting

May 6, 2019

Presented Positive Results from Two Phase 3 MicroStat (phenylephrine 2.5% / tropicamide 1% fixed combination ophthalmic solution) Trials

NEW YORK, May 06, 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 the safety and efficacy results from the Company's two Phase 3 trials, MIST-1 and MIST-2, for pharmacologic mydriasis (pupil dilation). The results were presented by David Wirta, M.D., from the podium during the joint American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) Annual Meeting, on May 5, 2019 in San Diego, CA.

The MIST-1 study enrolled 64 subjects, in whom both eyes were treated on separate days with MicroStat, Eyenovia's proprietary fixed combination, microdosed ophthalmic solution and with each component formulation (i.e. tropicamide and phenylephrine). The MIST-2 study enrolled 70 subjects, in whom both eyes were treated on separate days with MicroStat and a placebo solution. All treatments in the MIST-1 and MIST-2 trials were administered using Eyenovia's Optejet™ dispenser that allows for dosing of approximately 8 microliters, which is less than 25% of the dose volume typically administered with eye dropper bottles.

In each trial, MicroStat was shown to be safe and effective for pharmacologic mydriasis achieving clinically and statistically superior mean pupil dilation. Collective results show approximately 94% of treated eyes achieved pupil dilation of at least 6mm at 35 minutes post-instillation. Dilation was rapid in most patients, with up to 64% of fixed-combination treated eyes achieving 6mm or greater dilation as early as 20 minutes post-installation. Adverse events were infrequent (~3% of subjects), transient, and generally mild in nature.

Dr. Wirta, principal investigator of the MIST-1 study, said, "We believe these outcomes further validate ocular microdosing and demonstrate that less can be more – less preservative and medication exposure still delivers a compelling ocular biologic effect while sparing the ocular surface from the toxicity associated with preservatives and some topical medications."

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer, added, "The conclusion of our two Phase 3 registration studies for MicroStat mark significant progress in Eyenovia's pipeline. They validate the experience from our prior micro-dosing Phase II studies and are informative and enabling for our forthcoming Phase III trials in myopic progression and glaucoma. We believe the Optejet high-precision piezo-print delivery platform can improve the therapeutic index and tolerability of many ophthalmic therapies –unlocking the potential of ocular microdosing."

Terry Kim, M.D., member of Eyenovia's Scientific Advisory Board and ASCRS Treasurer, commented, "In addition to quick and reliable efficacy and an excellent safety profile, MicroStat may offer additional benefits, including the potential to minimize cross-contamination seen with dropper bottles because its unique dispenser has a non-protruding nozzle for no-touch spray application. I am excited for the potential of this innovative product to enhance my clinic's efficiency and improve my patients' experience."

All educational content of the ASCRS•ASOA Annual Meeting is planned by its program committee, and ASCRS•ASOA does not endorse, promote, approve, or recommend the use of any products, devices, or services.

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 mydriasis, myopia progression, glaucoma, and other eye diseases. For more Information please visit www.eyenovia.com.

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: NDA Filing 2020

About MicroPine for Progressive Myopia
MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye disease. Progressive myopia is estimated to affect close to 5 million patients 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: MicroPine Phase III Trial Start 2019

About MicroProst for Glaucoma and Ocular Hypertension
MicroProst is Eyenovia's proprietary latanoprost formulation product candidate, which is being developed as a first-line treatment for the reduction of IOP in patients with Chronic Angle Closure Glaucoma (CACG), as well as Primary Open Angle Glaucoma (POAG) and Ocular Hypertension. Currently, there are no FDA-approved therapies specifically indicated for CACG, which accounts for an estimated 10% and 50% of all glaucoma diagnoses in the United States and China, respectively. We believe there are approximately 500,000 patients with CACG in the United States and approximately 3.0 million with POAG for whom chronic, often life-long medication therapy is required.

Feasibility Dose-Finding Studies: MicroProst Phase II EYN PG21
Upcoming Milestone: MicroProst Phase III Trial Start 2019

About MicroTears OTC for Hyperemia, Pruritis and Dry Eye
MicroTears is a micro-droplet ocular hyperemia (red eye), pruritis (itch) and ocular lubrication product candidate for the approximately $850 million annual OTC artificial tear market in the United States.

Upcoming Milestone: OTC Monograph Registration 2019

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. 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: risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our need and ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies for existing product candidates and our ability to identify new product candidates; the potential advantages of our 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; 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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