Eyenovia Announces Positive Results in the MicroStat MIST-1 Phase III Registration Study for Mydriasis

January 30, 2019

MIST-1 study met primary endpoint

First-in-class fixed combination mydriatic agent demonstrated robust efficacy, high tolerability; Study further validates OpteJet™ platform delivery technology

Company to host conference call at 8:30 AM ET on January 30, 2019

NEW YORK, Jan. 30, 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 positive results from the MicroStat Phase 3 MIST-1 study. The study examined the safety and efficacy of the Company's first-in-class, MicroStat fixed-combination formulation, with target markets including the estimated 80 million annual pharmacologic mydriasis market in the United States.

The study was a U.S.-based, randomized, double-masked, superiority trial that enrolled 64 subjects, in whom both eyes were treated on separate days with Eyenovia's proprietary MicroStat fixed combination formulation of phenylephrine 2.5% - tropicamide 1%. MicroStat was compared against each component formulation of tropicamide and phenylephrine, respectively. All treatments were administered using Eyenovia's OpteJet technology.

For the primary efficacy outcome of mean pupil dilation at 35 minutes post-administration, the MicroStat group demonstrated a statistically and clinically superior mydriatic effect as compared to either component formulation. Additional outcomes demonstrated 94% of eyes achieved 6 mm or greater pupil dilation at 35 minutes post-administration. This compared with 78% and 1.6% for the tropicamide-only and phenylephrine-only groups, respectively. At 20 minutes, 57% of the MicroStat-treated eyes achieved 6 mm dilation or greater versus 38% of the tropicamide treated eyes and none in the phenylephrine treated eyes.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "We are excited with the results of the Phase 3 MIST-1 study. The MicroStat fixed-combination administered with the OpteJet delivered strong efficacy and was well tolerated by all subjects. We believe this is the first time in a Phase III FDA registration program that drugs have been delivered to the ocular surface using a smart microdose eyedropper-free delivery system – a meaningful step forward as we try to modernize the legacy eyedropper paradigm. These data from a well-controlled FDA registration study further validate our microdose technology platform and support our extensive clinical development pipeline for other microdosed ophthalmic solutions. We look forward to announcing topline data from our MIST-2 study in short order."

Dr. David Wirta, MD, principal investigator of the MIST-1 study added, "There are an estimated 80 million in-office exams performed each year in the United States requiring mydriasis, an integral part of comprehensive eye exams. Eyenovia's MIST-1 study results demonstrate that not only does MicroStat successfully induce significant pupil dilation, but it does so rapidly. We believe that having a fixed combination option to achieve mydriasis has the potential to streamline the in-office examination process, potentially increasing physician efficiency and patient through-put volume."

The Company expects to present the detailed results from the MIST-1 trial in a forthcoming scientific forum.

Conference Call Information

Eyenovia will host a conference call and webcast with slides today, January 30, 2019 at 8:30 AM Eastern to discuss the topline results of the MIST-1 study. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 2699153. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenoviabio.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 February 6, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 2699153.

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.eyenoviabio.com.

About MicroStat for Mydriasis
MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (phenylephrine-tropicamide) 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 help improve efficacy, usability and tolerability of pharmacologic mydriasis.

Feasibility Dose-finding Studies: MicroStat Ph I/II; MicroStat Ph II
Upcoming Milestone: NDA Filing In Q1 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 (Independent Collaborative Group Trials)
Upcoming Milestone: MicroPine Phase III Trial First Patient In H1 2019

About MicroProst for Glaucoma
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 Ocular Hypertension and Primary Open Angle Glaucoma (POAG). 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 close to 700,000 patients with CACG in the United States and more than 3.5 million with POAG for whom chronic, often life-long medication therapy is required.
Feasibility Dose-Finding Studies: MicroProst Phase II PG21
Upcoming Milestone: MicroProst Phase III Trial First Patient In H1 2019

About MicroTears OTC for Dry Eye
MicroTears is a micro-droplet ocular surface tear replenishment product candidate for the estimated $2 billion+ (200 million units) global annual OTC artificial tear market.

Upcoming Milestone: OTC Registration H1 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 in less than 80 milliseconds beating the ocular blink reflex. The OpteJet's targeted delivery system has demonstrated 85% topical delivery efficacy compared to 40-50% with the conventional eyedropper, and 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 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, and to raise money, including in light of U.S. government shut-downs; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies; 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; the impact of government laws and regulations; 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.

Caution: New Drug—Limited by Federal (United States) law to investigational use.

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