Eyenovia Announces FDA Acceptance of MicroStat IND Application for Mydriasis

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Company on track to initiate Phase III trials in late November

NEW YORK, Nov. 13, 2018 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver micro-dosed medications topically to the eye, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application to initiate Phase III trials of MicroStat for diagnostic mydriasis.

MicroStat is a first in class fixed-combination of phenylephrine and tropicamide for in office mydriasis (pupil dilation), a standard part of the approximately 80 million comprehensive exams performed every year in the United States. In an earlier published Phase II study, MicroStat, in combination with the Optejet™ dispenser, demonstrated consistent micro-dose delivery while also achieving therapeutic levels necessary for pupil dilation. With the acceptance of the IND, Eyenovia expects to initiate the Phase III trials of MicroStat later this month.

"We are very pleased to have received acceptance of our IND application for MicroStat from the FDA and are very excited to officially become a Phase III company," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "As our first clinical program to enter Phase III trials, the MicroStat program could provide important validation of our entire platform delivery technology. We look forward to initiating the trials in late November and expect to report topline results in the first half of 2019."

About Eyenovia
Eyenovia, Inc. (NASDAQ: EYEN) is a specialty biopharmaceutical company building a portfolio of next generation topical eye treatments based on its proprietary delivery and formulation platform for microdosing. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for myopia progression, glaucoma, mydriasis and other eye diseases.

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, obtain and maintain regulatory approvals for, our product candidates; 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.

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