Eyenovia Publication of EYE 102 Phase II Results Demonstrates Strong Pharmacodynamic Effect, Tolerability and Reduced Systemic Exposure of High-Precision Micro-dosing compared to Conventional Eyedroppers

Results published online ahead of print in peer-reviewed publication Therapeutic Delivery

EYE 102 marks second Phase II study demonstrating benefit of micro-therapeutic approach

New York – October 30, 2017 – Eyenovia Inc., a clinical-stage ophthalmic pharmaceutical company focused on the discovery, development, and commercialization of potential first-in-class micro-therapeutics for the eye, today announced that the positive results of its EYE 102 Phase II study have been published online ahead of print in the peer-reviewed journal Therapeutic Delivery. The top-line results from this study, showing that the study met its primary endpoints, were first announced in a press release in December 2016.

The article, titled “High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine,” concludes that Eyenovia’s micro-dose delivery of topical phenylephrine achieves comparable dilation results with a dose one-quarter the volume of a conventional pipette eye dropper. Additionally, the micro-dose delivery method showed less systemic absorption and no detectable impact on cardiovascular function.

“Micro-dosing avoids medication spillage from overloading the eye’s maximum tear volume of 7–10 μL, which is routinely exceeded by conventional eye dropper-delivery – overdosing the eye by more than 300% compared to physiologic tear film capacity. Reducing the volume avoids potential complications and may increase local absorption by reducing drug dilution from tears and tear loss due to blinking and drainage,” commented Dr. Louis R. Pasquale, MD, FARVO, Professor of Ophthalmology at Harvard Medical School and co-author of the study manuscript. “The trial confirmed that micro-dosing is as effective in dilating the eyes as conventional eye dropper-delivery. Furthermore, the enhanced ocular uptake provided by micro-dosing reduced the portion of drug otherwise available for systemic absorption, which can minimize risk of unintended systemic side effects associated with topical therapies.”

The Phase II, masked, non-randomized, cross-over study evaluated 12 subjects who underwent pupil dilation with topical phenylephrine (PE) administered by a 32-μL eye dropper (at one of two concentrations: 2.5% or 10% formulation) in one eye and an 8-μL micro-dosing administered electronically (10% formulation) in the other eye. Pharmacodynamic results showed that micro-dosing achieved comparable peak dilation to 10% eye dropper-delivery and superior dilation to 2.5% eye dropper-delivery (p=0.009) at 75 minutes. In addition, the study assessed systemic absorption and found micro-dosing demonstrably reduced 20-minute plasma PE levels versus 10% eye dropper-delivery with reduced systemic absorption of PE. Regarding safety and adverse events, neither micro-dosing nor eye dropper treatment altered heart rate or blood pressure, and no adverse events resulted in a subject being discontinued from the study. In terms of local ocular effects, eye irritation occurred significantly less frequently with micro-dosing than 10% eye dropper-delivery. Separately, none of the 12 subjects reported any level of discomfort after micro-dosing administration.

“Following our earlier Phase II study in 102 subjects, the EYE 102 trial marks the second Phase II clinical program validating our high-precision micro-dosing technology as a compelling approach which can dramatically improve the therapeutic index of many front-of-the-eye therapies. This positions Eyenovia on a linear path toward the initiation of multiple Phase III micro-therapeutic programs in 2018 to address unmet needs in glaucoma, mydriasis and dry eye,” said Dr. Ianchulev, Eyenovia’s CEO. “High precision micro-dosing using our proprietary electronic piezo-print technology opens immense possibilities for
eHealth and patient monitoring, compliance tracking and communication, and customized treatment approaches. We look forward to sharing additional updates on the continued development of the platform.”

The EYE 102 study builds on and validates the results of the earlier Phase II trial published in the October 2016 issue of *Therapeutic Delivery* on the pharmacodynamic effect of Eyenovia’s micro-therapeutic approach.

**About Eyenovia**
Eyenovia is a specialty biopharmaceutical company building a portfolio of next generation topical eye treatments based on its proprietary delivery and formulation platform for micro-therapeutics. Eyenovia’s pipeline is currently focused on the late-stage development of micro-therapeutics for glaucoma and other eye diseases. For more information, visit [www.eyenoviabio.com](http://www.eyenoviabio.com).

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