# Eyenovia Announces Reclassification of MydCombi(tm) as Drug-Device Combination Product by FDA

October 25, 2021

*Genus Medical Technologies, LLC v. FDA legal case leads to agency-wide review and reclassification of eye cups, eye droppers, and ophthalmic dispensers*

*Company received Complete Response Letter with additional requests and is preparing necessary documents for expedited resubmission*

NEW YORK, Oct. 25, 2021 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that MydCombi, the company's proprietary, first-in-class combination microdose formulation of tropicamide and phenylephrine for in-office pupil dilation, has been reclassified as a drug-device combination product by the U.S. Food and Drug Administration (FDA) in a Complete Response Letter (CRL) for the company's new drug application (NDA) received on October 22, 2021.

Eyenovia will provide additional information to the FDA, as requested in the CRL, as soon as possible, including information necessary to meet additional requirements under *Genus Medical Technologies, LLC v. FDA*. *Genus* refers to a recent decision by the U.S. Court of Appeals for the District of Columbia Circuit which has resulted in an agency-wide reclassification by FDA of certain drugs to devices or to drug-device combination products. There were no issues raised related to the phase III clinical program for MydCombi.

"While we were surprised by the FDA's position in the CRL, given our original FDA designation, we understand the unusual situation created by the impact of the Genus case, which compelled an Agency-wide reclassification," stated Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "Fortunately, we had taken actions throughout the development of MydCombi to minimize the impact of a potential reclassification by the FDA. We are preparing additional documentation requested by the FDA and look forward to resubmitting our NDA in early 2022 for the FDA's review. Since the device used for MydCombi has commonality with that used in the MicroLine and MicroPine programs, we believe that the information submitted in support of MydCombi will pave the way in advance of those regulatory submissions. In fact, we are on track to initiate our second Phase III MicroLine study for presbyopia in the coming days."

The Company's current total pro forma cash balance is approximately $30.7 million after the sale of approximately 1.8 million shares of common stock earlier this quarter through the Company's At The Market offering facility. The Company believes its total unrestricted and restricted cash balance will be sufficient for the resubmission of the NDA for MydCombi, completion of the MicroLine clinical program and other planned activities through the beginning of 2023.

Eyenovia announced FDA acceptance of the MydCombi NDA in March 2021. The NDA was based on the MIST-1 and MIST-2 studies. In these two Phase 3 studies, a fixed combination of micro-dosed tropicamide 1% and phenylephrine 2.5% ophthalmic solution met the studies' primary endpoints and was shown to be well-tolerated and effective for pharmacologic mydriasis. Approximately 94% of treated eyes achieved 6mm or greater dilation at 35 minutes post-instillation. Adverse events were infrequent, with fewer than 1% of patients reporting blurred vision, reduced acuity, photophobia or instillation site pain.

**About Eyenovia, Inc.**
Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. For more information, visit www.eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

**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 our ability to re-use the information in our NDA for MydCombi for the NDAs for MicroLine and MicroPine, the impact of the delay in FDA approval of MydCombi, acceptance by the FDA of our NDA resubmission for MydCombi, our ability to initiate our second Phase III MicroLine study for presbyopia, the sufficiency of our unrestricted and restricted cash for the resubmission of the NDA for MydCombi, completion of the MicroLine clinical program and other planned activities through the beginning of 2023. 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 in some cases 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 U.S. Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing of, and our ability to submit or re-submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology; 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; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies 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, Eyenovia does not undertake any obligation to update any forward-looking statements.

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