Eyenovia's MydCombi NDA Accepted by FDA

Eyenovia Announces FDA Acceptance of MydCombi NDA

March 02, 2021 – Eyenovia, Inc, a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, has announced that the FDA has accepted the company's New Drug Application NDA) for MydCombi™, a unique fixed combination mydriatic (pupil dilation) agent for potential use in comprehensive eye exams.

MydCombi™ was developed to address several challenges eye care practitioners and their patients face related to pupil dilation, including time for instillation of multiple drops, patient discomfort and drug overflow. MydCombi™ is delivered by Eyenovia's proprietary Optejet dispenser, designed to ensure consistency and ease of dispense of two mydriatic medications in a quick, touchless micro-mist application.

The NDA submission was based on two Phase 3 studies, MIST-1 and MIST-2. The studies met their primary endpoints and was shown to be safe and effective for pharmacological mydriasis.

Eyenovia under partnership with the Clinical Vision Research Center in August 2021 and March 2022 tested the clarity and usability of their MydCombi™ Optejet dispenser Instructions for Use (IFU) and Base Charging and Electrical IFU in realistic use scenarios but under simulated conditions of use.

"If approved, we believe MydCombi™ would provide patients with one of the biggest advances in clinical mydriasis in the last few decades."
-Dr. Sean Ianchulev, CEO, CMO, Eyenovia

The expected PDUFDA date for the potential approval of MydCombi™ in 4th quarter of 2021.

If approved, MydCombi™ would be the first micro-dosed ocular therapeutic applied with a high precision smart ***delivery system, the*** *Optejet®*