



Press Release 7 February 2022

## **AEYE Health Reports Pivotal Clinical Trial Results of its AI Algorithm for the Autonomous Screening and Detection of More-Than-Mild Diabetic Retinopathy**

AEYE Health, an innovative ophthalmic technology company developing AI-based systems for the diagnosis and screening of eye diseases, is pleased to report the results from its pivotal FDA-clinical trial for the autonomous detection of more-than-mild diabetic retinopathy. The study was the first of its kind to evaluate whether AI software can accurately detect more-than-mild diabetic retinopathy using a single image per eye, obtained from either a desktop or handheld retinal camera.

Using a single image from each eye can simplify the diagnostic procedure and reduce screening time.

The observed AI results for each camera system:

Topcon NW-400 (desktop camera): 93.0% sensitivity, 91.4% specificity, >99% imageability

Optomed Aurora (handheld camera): 91.9% sensitivity, 93.6% specificity, >99% imageability

A single image per eye was used for both the desktop and the handheld cameras.

There are 35M diabetics in the US and over 420M worldwide who are at risk of developing diabetic retinopathy requiring an annual screening. Early diagnosis and intervention are key for sight-loss prevention. Over a third of diabetics over the age of 40 will develop diabetic retinopathy, however only 15%-50% of patients undergo screening.

Autonomous screening in primary care setting requiring only a single image per eye obtained from a cost-effective handheld camera can improve adherence to screening protocols and ultimately prevent blindness in diabetics at risk for vision loss.

AEYE Health is seeking FDA clearance for its autonomous screening solution for diabetic retinopathy. In addition, the company is preparing to publish its results in diagnosing glaucoma using digital fundus images.

Zack Dvey-Aharon, Ph.D., CEO of AEYE Health commented:

“To truly revolutionize diagnostic screening for diabetic retinopathy, it is crucial to make the process accessible, affordable and highly accurate. The ability to accurately detect more-than-mild diabetic retinopathy using just a single image per eye, obtained from either desktop or handheld cameras is the true key to that revolution. AEYE is committed to deliver on this promise, as millions keep losing their vision from a preventable cause.”

Dr. Ianchulev, Professor of Ophthalmology at New York Eye and Ear of Mount Sinai and Board member of AEYE Health, sees enormous promise in the company’s technology:

“These are exciting times for ophthalmology and population health, as we see high efficacy of AI-based diagnostic approaches which can lead to scalable, almost exponential applications in the screening of eye disease and prevention of blindness.”

### **About AEYE Health**

AEYE Health is a digital health company that provides fully autonomous, AI-based diagnostic screening solutions for retinal imaging with best-in-class clinical results. The company aims to make diagnostic screening practical, accurate and accessible.

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