News Release

LARGE UK NATIONAL HEALTH SERVICES (NHS) STUDY FINDS EYEART DEVICE TO BE MOST SENSITIVE AUTOMATED RETINAL IMAGE ANALYSIS TECHNOLOGY FOR DIABETIC RETINOPATHY SCREENING

WOODLAND HILLS, Calif. – May 2, 2016 – Eyenuk, Inc., developer of advanced retinal image analysis solutions to identify eye disease, today announced results from the first large-scale, independent, comparative study of automated diabetic retinopathy (DR) screening technologies, showing that its EyeArt™ software device rated highest among those tested in sensitivity across all types of DR. The study results were presented yesterday by Catherine Egan, MD, Consultant Ophthalmologist, Moorfields Eye Hospital, London in an oral presentation at the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO).

The study investigators concluded that EyeArt achieved acceptable sensitivity for referable retinopathy when compared with a quality-assured, real world human grader working in a high volume clinical setting as a reference standard, and had specificity sufficient to make it a cost effective alternative to a purely manual grading approach.

The study of 142,018 images from 20,258 consecutive patients reviewed three CE marked automated retinal image analysis software solutions for effectiveness and cost-effectiveness. The study was funded by the National Institute for Health Research HTA program, a Fight for Sight grant, and the Department of Health's NIHR Biomedical Research Centre for Ophthalmology at Moorfields Eye Hospital.

The sensitivity results were as follows:

	Any Retinopathy	**Referable Retinopathy**	**R3 Proliferative Retinopathy**
EyeArt 1.0	94.7% [95% CI: 94.2-95.2%]	93.8% [95% CI: 92.9-94.6)	99.6% [95% CI: 97.0-99.9%]
Retmarker	73.0% [95% CI: 72.0-74.0%]	85.0% [95% CI: 83.6-86.2%]	97.9% [95% CI: 94.9-99.1%]
iGradingM	All images classified as either having disease or being ungradable; this limited further analysis.		

"The first large-scale, independent study of automated DR screening technologies showed that automation, such as that provided by EyeArt, can not only increase our screening capability, but do it with very high levels of sensitivity," said Adnan Tufail, MD, FRCOphth, principal investigator of the study and Consultant Ophthalmologist with Moorfields Eye Hospital, London. "Our comprehensive health economic analysis further showed that this type of novel technology can be a cost effective alternative to purely manual grading."

While the NHS study employed EyeArt version 1.0, the first study of the second generation of EyeArt device (version 2.0) was also presented at ARVO, which demonstrated both sensitivity and specificity over 90 percent. This study, co-authored by SriniVas Sadda, MD, President and Chief Scientific Officer of the Doheny Eye Institute, Los Angeles, and Jorge Cuadros, OD, PhD, Assistant Clinical Professor, University of California, Berkeley School of Optometry, encompassed color fundus images of 30,314 consecutive diabetic patient visits and reported EyeArt 2.0 sensitivity of 92.3 percent [95% CI: 91.6 - 93.0%] with specificity of 90.4 percent [95% CI: 90.0 - 90.8%] for referable DR.

“Current manual DR screening setups cannot scale to triage the ever-growing diabetic population at risk of vision loss,” said Dr. Sadda. “By automatically analyzing retinal images and instantly providing a refer/no-refer recommendation with high levels of sensitivity and specificity as demonstrated by our large real-world, consecutive patient study, EyeArt is expected to facilitate a fundamental shift in how patients with DR can be identified.”

“By fully automating the entire screening process, including imaging, grading, and reporting in a single office visit, we have combined speed and accuracy into what we believe is the most advanced DR screening technology available,” said Eyenuk Chief Executive Officer, Kaushal Solanki, PhD. “The technology is also designed to work effectively with image quality commonly found in diabetes patients and with imaging protocols/cameras typically used in screening setups, providing utmost flexibility to users.”

ABOUT EYENUK, INC.

Eyenuk, Inc., headquartered in Los Angeles, California, is focused on quickly and accurately identifying patients suffering from potentially blinding eye diseases and preserving their vision. Using computer vision and image analysis expertise, the company is developing a portfolio of products based on its proprietary retinal image analysis technology to identify and track the progression of eye diseases, including diabetic retinopathy and age-related macular degeneration (AMD). For more information, visit www.eyenuk.com.

EyeArt™ has received the CE Marking and is commercially available in the European Union. In the United States, EyeArt™ is limited by federal law to investigational use only and is not available for sale.

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