News Release

Eyenuk, Inc. Receives Health Canada Approval for EyeArt™, an AI-enabled Cloud-based Automated Diabetic Retinopathy Screening Software

Eyenuk's quality management system has been registered under the Medical Device Single Audit Program ("MDSAP") as conforming to the requirements of ISO 13485:2003, after successfully completing an audit for the relevant quality management system requirements of the U.S. Food and Drug Administration and Health Canada.

Eyenuk, Inc., a leading developer of advanced artificial intelligence (AI) enabled, clinically supported solutions to identify diseases via retinal image analysis, today announced that it has received a Medical Device License from Health Canada for its AI-enabled cloud-based diabetic retinopathy (DR) automated screening software system, EyeArt™ (v2.1.0). The Canadian Medical Device License allows Eyenuk to begin commercializing EyeArt™ and begin sales throughout Canada. Building upon Eyenuk's successful launch in Europe, this Health Canada license supports Eyenuk's objective to expand the global availability of EyeArt™ to more clinicians seeking tools for improved screening of diabetic retinopathy in their patients at the point of care.

A key breakthrough that EyeArt™ brings to clinics in Canada (and Europe) is that the software is indicated for use by health care professionals including nurses or technicians, and does not require expert human grading or an over-read from an eye care specialist. EyeArt™ screening software is designed to return results within 60 seconds and work with most fundus cameras that provide quality images. With EyeArt™, Eyenuk aims to make available a cost-effective approach to diabetic retinopathy screening that can be deployed at mass scales in the primary health care setting.

"We are very excited to launch the EyeArt™ screening software in Canada, building upon our impressive clinical results from Europe," said Kaushal Solanki, Founder and CEO of Eyenuk." Access to eye screening is limited and expensive for many patients and as a result diabetic retinopathy is the leading cause of preventable blindness, especially impacting working-age adults across the world. We are proud to expand EyeArt™ to additional countries in an effort to make diabetic eye screening more accessible, more efficient, and less expensive, thereby reducing the number of patients losing vision as a complication of diabetes."

EyeArt™ has CE marking in the European Union and now has a Medical Device License in Canada. The technology is currently being used commercially in Europe and as an investigational device at prestigious clinical institutions across the United States.

In addition to receiving the Canadian Medical Device License, Eyenuk, Inc. is proud to announce that the quality management system of the company has been registered by Intertek Testing Services NA, Inc., a Medical Device Single Audit Program ("MDSAP") recognized auditing organization, as conforming to the requirements of ISO 13485:2003 for the design and development, product, installation and service of stand-alone image analysis software for retinal diseases or disorders.

In order to receive ISO 13485:2003 certification, an entity must demonstrate to an authorized third party that it meets or exceeds the requirements for a comprehensive medical device management system. MDSAP allows a single audit of an entity's management system by an MDSAP recognized auditor to satisfy the relevant regulatory requirements of the U.S. Food and Drug Administration and Health Canada, as well as the requirements of the relevant regulatory authorities in Australia, Brazil, and Japan, which are the other countries that participate in

MDSAP. Eyenuk's MDSAP audit covered the relevant quality management system requirements of ISO 13485:2003, the U.S. Food and Drug Administration and Health Canada.

About Diabetic Retinopathy

Diabetic retinopathy (DR) is a blinding eye disease which can affect many of the 415 million patients living with diabetes worldwide. Vision loss due to DR is preventable, if diagnosed early through annual eye screening. However, in many places the current number of eye care professionals cannot keep pace with the demand for annual eye screening, making DR the leading cause of blindness among working-age adults in the industrialized world. Experts have recognized that the only feasible way to address this issue is to efficiently expand DR screening in the primary care environment via computerized analysis.

About Eyenuk, Inc.

Eyenuk, Inc., headquartered in Los Angeles, California, is an AI diagnostic company focused on quickly and accurately identifying patients suffering from potentially blinding eye diseases and chronic diseases at the point of care. Using computer vision and machine learning expertise, the company is developing a portfolio of products based on its proprietary retinal image analysis technology combined with deep learning to identify and track the progression of diseases including diabetic retinopathy, glaucoma, age-related macular degeneration, risk of stroke, cardiovascular risk, and Alzheimer's disease.

Eyenuk's first product to market, EyeArt™, is a fully-automated cloud-based software device for screening of diabetic retinopathy, the leading cause of blindness in working- age adults. EyeArt™ has received a Medical Device License from Health Canada and CE marking in the European Union. In the United States, EyeArt™ is limited by federal law to investigational use only and is not available for sale.

For more information on Eyenuk, Inc. and the EyeArt™ automated software system, please visit www.eyenuk.com. EyeArt™ is a trademark of Eyenuk, Inc.

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