RETINA-AI Health, Inc. Announces Positive Pivotal Study Results for the RETINA-AI Galaxy™ Autonomous Diabetic Retinopathy Screening Device. Regulatory Application Submitted to the FDA for Clearance.

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RETINA-AI Health, Inc. →
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HOUSTON, Sept. 20, 2021 /PRNewswire/ -- RETINA-AI Health, Inc. today announced positive results from the pivotal study of the RETINA-AI Galaxy™, a multi-device compatible autonomous diabetic retinopathy screening device intended for use in primary care settings. Furthermore, the company announced that it has submitted its application to the U.S. Food and Drug Administration (FDA) for clearance.

The pivotal clinical study results were presented today at the Society for Imaging Informatics in Medicine (SiiM)'s Conference on Machine Intelligence in Medical Imaging (CMIMI21). The presentation was titled: *Clinical Validation of a Multi-Device Compatible Artificial Intelligence System for Diabetic Retinopathy Screening in the Primary Care Setting.*

The RETINA-AI Galaxy device has been submitted to the U.S. Food and Drug Administration (FDA) for review.

The multi-center, multi-device observational study (ClinicalTrials.gov ID: NCT04774822) recruited subjects from four primary care sites. Clinical performance of the RETINA-AI Galaxy™ software as a medical device (SaMD) was assessed on five robotic fundus cameras: CenterVue DRSPlus, Crystalvue NFC-700, NextSight Nexy, Topcon NW400, and CenterVue DRS. These five studies, one per camera, were run in parallel. For each camera, 397 subjects aged 22 years or above and who had diabetes were recruited. All data was prospectively obtained. Intent to screen ranged from 383-385 depending on camera. Primary endpoints were sensitivity and specificity of more than mild diabetic retinopathy (mtmDR) and sensitivity and specificity of vision threatening diabetic retinopathy (vtDR). mtmDR was denoted as Early Treatment of Diabetic Retinopathy Severity Scale (ETDRS) ≥35 (but not 90) and/or Clinically Significant Diabetic Macula Edema (CSDME). vtDR was denoted as ETDRS ≥53 (but not equal to 90) and/or CSDME. Grading was done by American Board Certified Ophthalmologists who are fellowship trained in retina (retina specialists) at the Retina Reading Center (RRC). A probabilistic grading schema based on level of agreement amongst graders was used to quantify grades. And a declarative assignment of mtmDR := Probable mtmDR and vtDR := possible vtDR was used.

A blinded assessment was conducted as was computation of the Receiver Operator Characteristic (ROC) curves. For mtmDR, sensitivity of the RETINA-AI Galaxy™ at or above 82.5% specificity was as follows:

On DRSPlus, sensitivity = 95% and specificity = 82.8%
On Crystalvue NFC700, sensitivity = 89.2% and specificity = 82.5%
On Nexy, sensitivity = 83.6% and specificity = 82.6%
On Topcon NW400, Sensitivity = 87.3% and Specificity = 83.2%
On DRS, Sensitivity 88.2% and Specificity = 85.3%

For vtDR, sensitivity of the RETINA-AI Galaxy™ at or above 82.5% specificity was as follows:

On DRSPlus , sensitivity = 97.1%, specificity = 84%
On Crystalvue NFC-700, sensitivity = 88.2%, specificity = 88.1%
On Nexy, sensitivity 94.1%, specificity 90.9%
On Topcon NW400, sensitivity = 93.9%, specificity 94.8%
On DRS, sensitivity = 94.1% and specificity = 85%.

Imageability was 99.2% on the DRSPlus, Crystalvue NFC-700, and Nexy; 96.5% on the Topcon NW400, and 94% on the DRS.

All primary endpoints were met.

The RETINA-AI Galaxy device attained a sensitivity was 100% on all 5 cameras for definite vtDR, probable vtDR, and vtDR in the absence of CSDME, each with specificity at or above 82.5%.

Dr. Stephen G. Odaibo, RETINA-AI Health Inc.'s Founder and CEO, himself a computer scientist, AI/ML expert, and retina specialist stated that "Diabetes affects over 35 million Americans and 450 million people globally. And each diabetic patient requires an annual eye exam, but most do not receive it due to multiple factors. Artificial Intelligence can play a significant role in increasing access to care, but till now there has been a serious lack of fundus camera options that have undergone rigorous validation for use as accessories to autonomous AI systems. This is the first such study that assesses an autonomous AI system on cameras from multiple manufacturers." The RETINA-AI Galaxy™ device has been submitted to the FDA for review.

ABOUT RETINA-AI Health, Inc.
RETINA-AI Health, Inc. is a privately-held Delaware C-Corp founded in 2017 and headquartered in Houston Texas. The company is focused on building AI to transform healthcare and improve the outcomes of prevalent chronic diseases. It develops and deploys retina-based AI for detection of systemic chronic diseases at scale. RETINA-AI Health, Inc. has a strong unwavering commitment to adhere to the highest standards of quality and ethics, while continuously leading the world in healthcare AI innovation.

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