FOR IMMEDIATE RELEASE
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Siloam Vision Reports Positive Pivotal Clinical Study Results for iROP-Assist™ AI-Powered Platform for Retinopathy of Prematurity Diagnosis

Prospective, masked multi-reader, multi-case (MRMC) study demonstrates statistically significant improvements in diagnostic accuracy and inter-reader agreement for plus disease in retinopathy of prematurity (ROP) images.

PORTLAND, OR, April 14, 2026 – Siloam Vision, Inc., a medical device company developing artificial intelligence-powered tools for ROP, today announced positive top-line results from its pivotal clinical study evaluating iROP-Assist™, an assistive, clinician-in-the-loop AI decision-support platform for ophthalmologists interpreting ROP exams in the neonatal intensive care unit (NICU).

The prospective, masked, multi-reader, multi-case (MRMC) study met its primary endpoint, demonstrating a statistically significant improvement in diagnostic accuracy for plus disease when clinicians used iROP-Assist™ compared to standard clinical interpretation without AI assistance. The study also met all key secondary endpoints, showing meaningful improvements in diagnostic agreement for pre-plus and plus disease across readers, and improved consistency of 1-9 "P score" grading.

About the Study

The study enrolled 16 board-certified ophthalmologists with varying levels of ROP expertise, including pediatric ophthalmologists and retina specialists. Each reader independently evaluated 300 ROP examinations (5 images per examination) acquired using the RetCam™ imaging system, first without AI assistance.

Following a minimum one-month washout period, readers re-evaluated the same cases with access to the iROP-Assist™ AI-derived vascular severity score (VSS).

The study assessed clinician performance in:
- Classifying plus disease and pre-plus disease
- Grading disease severity using a continuous 1–9 "P-score" scale

Performance was measured against a reference standard defined by consensus grading from five expert readers.

Key Results

iROP-Assist™ demonstrated statistically significant improvements across the following pre-specified endpoints:

Primary Endpoint:
- Improved diagnostic accuracy for plus disease (mean AUC: 0.93 vs 0.95, $p < 0.001$)

Secondary Endpoints:
- Improved consistency in P score grading (ICC: 0.76 vs 0.86, $p<0.001$)
- Increased inter-reader agreement for plus disease (κ: 0.55 vs 0.62, $p<0.001$)
- Improved diagnostic accuracy for pre-plus (or worse) disease: mean AUC: 0.94 (range 0.90-0.95) vs 0.96 (range 0.92-0.96), $p<0.017$)
- Increased inter-reader agreement for pre-plus (or worse) disease (κ: 0.61 vs 0.65, $p=0.002$)

"These results validate what we observed in earlier studies—by objectively quantifying the spectrum of vascular disease, iROP-Assist™ improves diagnostic agreement not only for plus disease as a category, but also for continuous severity assessment using the P-score," said **J. Peter Campbell, MD, MPH**.

Clinical Significance

ROP is a leading cause of childhood blindness worldwide, affecting premature infants whose retinal vasculature has not fully developed at birth. Plus disease—characterized by abnormal dilation and tortuosity of the posterior retinal vessels—remains the primary clinical determinant for treatment decisions.

Despite its importance, diagnosis of plus disease has long been limited by substantial inter-expert variability, even among highly trained specialists.

"The level of inter-reader variability in ROP diagnosis is a patient safety issue that the field has grappled with for years," said **R.V. Paul Chan, MD, MSc, MBA**. "This study provides evidence that an AI tool can meaningfully narrow that gap at scale, across readers with very different experience profiles."

Improved diagnostic consistency has the potential to reduce both missed cases of treatment-requiring disease and unnecessary interventions, supporting more standardized and equitable care for premature infants.

Technology Background

iROP-Assist™ utilizes the "i-ROP" deep learning algorithm, developed through a decade of NIH-funded research at Harvard Medical School, Oregon Health & Science University, Northeastern University, and the University of Illinois, Chicago. The research was led by **Michael Chiang, MD**, now the director of the National Eye Institute, and **Jayashree Kalpathy Cramer, PhD,** now the Director of Artificial Medical Intelligence at the University of Colorado. The clinical study was supported by an NIH phase II SBIR grant.

Regulatory Pathway

Siloam Vision plans to submit these pivotal study data as part of a De Novo premarket submission to the U.S. Food and Drug Administration later this year. At this time, iROP-Assist™ has not been FDA cleared, though it has previously received FDA Breakthrough Device Designation.

About Siloam Vision, Inc.

Siloam Vision is a Portland, Oregon-based medical device company dedicated to reducing preventable blindness through advanced imaging and artificial intelligence.

For more information, visit www.siloamvision.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties.

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