May 5, 2025

Detailed Results From B-Series OCT with ImgAssist AI 2.0 Pivotal Trial Presented at ASBrS 2025

– First-ever successful pivotal trial of a new intraoperative margin assessment technology in breast cancer –

– Pivotal trial met its primary endpoint with statistically significant reduction in patients with residual cancer during surgery (p-value = 0.0050) and demonstrated super-superiority compared to standard-of-care alone–

– ASBrS presentation highlighted both these previously reported positive topline results and new additional analyses, including secondary endpoints and additional reporting –

TORONTO and DALLAS, May 5, 2025 /CNW/ - Perimeter Medical Imaging AI, Inc. (TSXV: PINK) (OTCQX: PYNKF) ("Perimeter" or the "Company"), a commercial-stage medical technology company, is pleased to announce detailed results from the pivotal trial evaluating the use of its next-generation B-Series OCT with ImgAssist AI 2.0 ("Perimeter B-Series" or "OCT-AI") for intraoperative margin assessment during breast-conserving surgeries ("BCS").

The positive pivotal trial results were presented this past Saturday during the scientific session of the 26th Annual Meeting of the American Society of Breast Surgeons("ASBrS") by Dr. Alastair Thompson, the trial's Primary Principal Investigator, Surgeon and Professor, Section Chief of Breast Surgery, Olga Keith Wiess Chair of Surgery at Baylor College of Medicine, Breast Cancer Program Leader at the Dan L Duncan Comprehensive Cancer Center.

Dr. Thompson commented, "Today, intraoperative margin assessment remains one of the most pressing problems for both surgeons and their patients. The final results of this pivotal trial clearly demonstrate that the use of Perimeter B-Series has the potential to change the current paradigm by empowering surgeons to identify regions of interest, enhance real-time intraoperative decision-making, and reduce the incidence of re-excision due to unaddressed residual disease following lumpectomy."

Dr. Thompson's ASBrS presentation highlighted:

Primary Endpoint

- Of the 206 patients evaluated, 56 residual diseased margins in 35/206 patients remained after intraoperative Standard of Care (SOC) alone (17.0% patients with residual diseased margins).

- Use of Perimeter B-Series after SOC evaluation resulted in correct detection of residual disease in 14/35 (40.0%) additional patients, fully clearing 7/35 (20.0%) additional patients of all residual disease, and meeting the prespecified super-superiority performance goal for the primary endpoint (P=0.0050).

- Mean total lumpectomy tissue volume excised in the device arm of the trial was 74.0 cm^3: 76.4% (56.5 cm^3) of the volume was from the primary lumpectomies, 19.9% (14.7 cm^3) from 499 SOC shaves, and only 3.8% (2.8 cm^3) from 115 Perimeter B-Series shaves.

- The overall Perimeter B-Series margin accuracy was 88.1%.

Clinical Benefit

In total, 26 patients benefited clinically from the identification of residual disease by OCT-AI after SOC was completed. Importantly, this includes six patients with Perimeter B-Series-aided shaves which contained pathology-confirmed disease missed by both SOC and histopathology at the previous margin.

"We believe Perimeter B-Series will empower surgeons to more effectively identify and address residual cancer at the margin — removing less healthy tissue, reducing re-operations, and sparing breast cancer patients the anxiety of waiting days for post-op pathology results. The goal of interoperative margin assessment with OCT-AI is a single, successful surgery so these patients can return to their lives and loved ones sooner," said Perimeter's Chief Executive Officer, Adrian Mendes. "We are deeply grateful to the clinicians, researchers, and especially the breast cancer patients that participated in the pivotal trial."

In March 2025, Perimeter announced the submission of a Premarket Approval ("PMA") application to the U.S. Food and Drug Administration ("FDA") for use of Perimeter B-Series during BCS in the United States. The FDA PMA submission represents the achievement of a major milestone – Perimeter's first pre-market regulatory submission for its AI-enabled wide-field OCT technology, as well as for a specific indication label. The PMA including the pivotal study results are currently under review with the FDA.

About the B-Series OCT with ImgAssist AI 2.0 Pivotal Trial

In this prospective, multi-center, randomized, clinical trial, 206 breast cancer patients undergoing BCS for the treatment of Stage 0-III invasive ductal carcinoma and/or ductal carcinoma in situ were evaluated to measure the effectiveness of the Perimeter B-Series as compared to lumpectomy current standard-of-care ("SOC") methods including palpation, specimen radiograph, intraoperative pathology and ultrasound in addressing positive margins. Participants were recruited from multiple clinical sites across the United States. There were no unanticipated device-related or serious adverse events reported in the pivotal trial.

About Perimeter Medical Imaging AI, Inc.

Based in Toronto, Canada and Dallas, Texas, Perimeter Medical Imaging AI (TSX-V: PINK) (OTCQX: PYNKF) is a medical technology company driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address areas of high unmet medical need. Available across the U.S., our FDA-cleared Perimeter S-Series OCT system provides real-time, cross-sectional visualization of excised tissues at the cellular level. The breakthrough-device-designated investigational Perimeter B-Series OCT with ImgAssist AI represents our next-generation artificial intelligence technology that was recently evaluated in a pivotal clinical trial, with support from a grant of up to US$7.4 million awarded by the Cancer Prevention and Research Institute of Texas. The company's ticker symbol "PINK" is a reference to the pink ribbons used during Breast Cancer Awareness Month.

Perimeter B-Series OCT is limited by U.S. law to investigational use and not available for sale in the United States. Perimeter S-Series OCT has 510(k) clearance under a general indication and has not been evaluated by the U.S. FDA specifically for use in breast tissue, breast cancer, other types of cancer, margin evaluation, and reducing re-excision rates. The safety and effectiveness of these uses has not been established. For more information, please visit www.perimetermed.com/disclosures.

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This news release contains statements that constitute "forward-looking information" within the meaning of applicable Canadian securities legislation. In this news release, words such as "may," "would," "could," "will," "likely," "believe," "expect," "anticipate," "intend," "plan," "estimate," and similar words and the negative form thereof are used to identify forward-looking statements. Forward-looking information may relate to management's future outlook and anticipated events or results and may include statements or information regarding the future financial position, business strategy and strategic goals, competitive conditions, research and development activities, projected costs and capital expenditures, research and clinical testing outcomes, taxes and plans and objectives of, or involving, Perimeter. Without limitation, information regarding the potential benefits of Perimeter S-Series OCT and Perimeter B-Series OCT, the expected benefits of Perimeter's updated version of its ImgAssist AI, and Perimeter's expectations regarding the outcomes of the clinical trial and future submission to the FDA are forward-looking information. Forward-looking statements should not be read as guarantees of future performance or results, and will not necessarily be accurate indications of whether, or the times at or by which, any particular result will be achieved. No assurance can be given that any events anticipated by the forward-looking information will transpire or occur. Forward-looking information is based on information available at the time and/or management's good-faith belief with respect to future events and are subject to known or unknown risks, uncertainties, assumptions, and other unpredictable factors, many of which are beyond Perimeter's control. Such forward-looking statements reflect Perimeter's current view with respect to future events, but are inherently subject to significant medical, scientific, business, economic, competitive, political, and social uncertainties and contingencies. In making forward-looking statements, Perimeter may make various material assumptions, including but not limited to (i) the accuracy of

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CONTACTS:

Stephen Kilmer
Investor Relations
Direct: 647-872-4849
Email: skilmer@perimetermed.com

Susan Thomas
Media Relations
Direct: 619-540-9195
Email: susan@endpointcommunications.net

Adrian Mendes
Chief Executive Officer
Toll-free: 888-988-7465 (PINK)
Email: investors@perimetermed.com

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