

Perimeter Medical Imaging AI Announces Initiation of First Clinical Trial Site at West Cancer Center & Research Institute in Tennessee

Pivotal study to determine the impact of Perimeter B-Series OCT with ImgAssist AI on positive margin rates during breast conservation surgery

TORONTO & DALLAS--(BUSINESS WIRE)-- Perimeter Medical Imaging AI, Inc. (TSX-V:PINK)(OTC:PYNKF) (FSE:4PC) ("Perimeter" or the "Company"), a medical technology company driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address high unmet medical needs, announced the initiation of a multi-center, randomized, two-arm pivotal clinical trial to evaluate its Perimeter B-Series OCT with ImgAssist AI for use during breast conservation surgery. The first patient procedures were performed by Richard E. Fine, MD and Michael Berry, MD, leading breast surgeons based out of the Margaret West Comprehensive Breast Center in Germantown, Tennessee.

Dr. Richard E. Fine, Director of Education & Research, Margaret West Comprehensive Breast Center, West Cancer Center & Research Institute, stated, "We are excited to be the first site to enroll a patient in the Perimeter pivotal trial that is evaluating the use of Perimeter B-Series OCT imaging technology combined with artificial intelligence. There is a strong unmet medical need to provide breast cancer surgeons with specimen imaging tools to aid their decisions 'real time' in the operating room. Through this pivotal study, we can assess if the Perimeter B-Series with artificial intelligence demonstrates an improvement over the current standard of care – potentially setting a new standard for specimen imaging technology during breast conservation surgery."

Dr. Michael Berry, Director of Margaret West Comprehensive Breast Center, commented, "Approximately 15% to 20% of women who undergo breast conservation surgery require reoperation if their surgeon fails to get clear margins. By combining optical coherence tomography with deep learning algorithms, this innovative technology could assist us, as surgeons, to better identify regions of interest on scanned samples, enabling 'real-time' decisions on margin status in the OR."

Jeremy Sobotta, Perimeter's Chief Executive Officer stated, "The initiation of this pivotal trial marks another milestone in our ATLAS AI project and an important step in the clinical development of our breakthrough-device-designated Perimeter B-Series OCT with AI assisted software, which represents the next generation of our commercially available flagship Perimeter S-Series OCT. Our hope is that clinical data generated from this study will provide supporting evidence that our technology can help breast cancer physicians improve outcomes for patients and potentially reduce the burden of additional costs within the healthcare system. We expect that this study will be completed by the end of 2022."

About West Cancer Center & Research Institute

West Cancer Center & Research Institute is a leader in adult cancer care guided by physicians to provide the most positive outcomes through research, novel therapies, advanced treatments, and cancer prevention to all patients, regardless of socioeconomic status. With over 40 years of oncology expertise, 100+ specialists, 8 locations including a breast center, and over 47,000 patients in 2020 - West is positioned as the first choice for cancer care in the Mid-South and a national model for comprehensive care.

About the Clinical Development of Perimeter B-Series OCT with ImgAssist AI

Perimeter is advancing the development of its proprietary, next-gen “ImgAssist” artificial intelligence (AI) technology under its ATLAS AI project, which is made possible, in part, by a US\$7.4 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT). The U.S. FDA granted Breakthrough Device Designation for Perimeter B-Series OCT + ImgAssist AI, which has the potential to aid surgeons in identifying regions of interest on scanned samples, enabling them to make key decisions on margin status real-time intraoperatively. A multi-center, randomized, two-arm clinical trial is underway to measure the effectiveness of the Perimeter B-Series OCT + ImgAssist AI in reducing the number of unaddressed positive margins in breast lumpectomy procedures when used in addition to standard intraoperative margin assessment. Approximately 300 patients undergoing breast conservation surgery across eight U.S. clinical sites will participate in the pivotal study led by Principal Investigator, Dr. Alastair Thompson at Baylor College of Medicine, with study completion anticipated by the end of 2022.

About Perimeter S-Series OCT

Cleared by the U.S. FDA with a general tissue indication, Perimeter S-Series Optical Coherence Tomography (OCT) is a novel medical imaging system that provides clinicians with cross-sectional, real-time margin visualization (1-2 mm below the surface) of an excised tissue specimen. Giving physicians the ability to visualize microscopic tissue structures “real time” in the operating room has the potential to result in better long-term outcomes for patients and lower costs to the healthcare system.

About Perimeter Medical Imaging AI, Inc.

With headquarters in Toronto, Canada and Dallas, Texas, [Perimeter Medical Imaging AI](#) (TSX-V:PINK) (OTC:PYNKF) (FSE:4PC) is a medical technology company that is driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address areas of high unmet medical need. The company’s ticker symbol “PINK” is a reference to the pink ribbons used during Breast Cancer Awareness Month, underscoring the company’s dedication to helping surgeons, radiologists, and pathologists use Perimeter’s imaging technology and AI in the fight against breast cancer, which is estimated to [account for 30%](#) of all female cancer diagnoses this year.

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Forward-Looking Statements

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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, Perimeter B-Series OCT, and Perimeter ImgAssist (the “Products”); the estimated number of patients, U.S. clinical sites and anticipated completion date of Perimeter’s pivotal trial; research and development activities; as well as the Company’s plans for development of the Products is 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, such future performance 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 Perimeter’s financial projections; (ii) obtaining positive results from trials; (iii) obtaining necessary regulatory approvals; and (iv) general business, market, and economic conditions. Further risks, uncertainties and assumptions include, but are not limited to, those applicable to Perimeter and described in Perimeter’s Management Discussion and Analysis for the year ended December 31, 2020, which is available on Perimeter’s SEDAR profile at www.sedar.com, and could cause actual events or results to differ materially from those projected in any forward-looking statements. In particular, we note the risk that our technology may not achieve the anticipated benefits in terms of surgical outcomes. Perimeter does not intend, nor does Perimeter undertake any obligation, to update or revise any forward-looking information contained in this news release to reflect subsequent information, events, or circumstances or otherwise, except if required by applicable laws.

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