October 1, 2024

Perimeter Announces Completion of Patient Enrollment in Pivotal Clinical Trial Evaluating OCT B-Series with ImgAssist AI in Breast-Conserving Surgeries

– Perimeter OCT B-Series is the first system designed to combine AI with optical coherence tomography for margin assessment, with the aim of reducing the unacceptably high reoperation rates associated with BCS –

– Recent study[1] published in the Annals of Surgical Oncology revealed reoperation rates of 21.1% among commercially insured women and 14.9% among the Medicare cohort –

– Primary endpoint results from OCT B-Series pivotal trial expected in Q4-2024; could support submission to FDA in 2025 –

– First-ever marketing clearance for specific use in breast tissue, breast cancer, and margin evaluation, if obtained, would represent a major inflection point for Perimeter's business –

TORONTO and DALLAS, Oct. 1, 2024 /CNW/ - Perimeter Medical Imaging AI, Inc. (TSXV: PINK) (OTC: PYNKF) ("Perimeter" or the "Company"), a commercial-stage medical technology company, today announced the completion of patient enrollment in a pivotal study evaluating the use of its next-generation Perimeter B-Series OCT system, which combines proprietary artificial intelligence ("AI") technology with optical coherence tomography ("OCT"), during breast-conserving surgeries ("BCS").

Unfortunately, re-excision after BCS is a common problem with reoperation rates reported from 14 to 21%[1] due to missed margins and leaving cancer behind. If Perimeter's B-Series study is successful, it will have demonstrated a decrease in the number of patients where breast cancer was missed during surgery.

This prospective, multi-center, randomized, double-arm clinical trial enrolled approximately 530 women, aged 18 years and older, undergoing BCS for the treatment of Stage 0-III invasive ductal carcinoma and/or ductal carcinoma in situ. Participants were recruited from 10 clinical sites across the United States and randomized in a 2:1 ratio to the device and control arms.

Approximately 200 of these subjects will be used to evaluate the effectiveness of the Perimeter B-Series, which integrates OCT imaging with the ImgAssist 2.0 AI algorithm, in addressing positive margins as compared to the standard lumpectomy procedure. A within-subject analysis will be used to assess the primary endpoint, which is the occurrence of at least one unaddressed positive margin for a subject. In addition, several other analyses will be conducted, including evaluations of safety outcomes, cosmesis results, as well as secondary and exploratory endpoints that examine positive cancer results at the margin and patient levels.

"It is very exciting that the pivotal trial has completed enrollment in such a timely manner," said 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. "Today, intraoperative margin assessment remains one of the most pressing problems for both surgeons and their patients. Perimeter's AI technology empowers surgeons with a dedicated intraoperative tool to identify regions of interest and guide real-time decisions on margin status in the OR. The goal is to determine whether this technology can help lower re-excision rates – potentially setting a new standard for specimen imaging technology during BCS. There has been a smooth collaboration between the clinical trial sites and Perimeter, and we all are looking forward to seeing the final results."

"We are pleased patient enrollment has now been completed and look forward to sharing the primary endpoint results of this pivotal study with our stakeholders prior to the end of 2024," commented Adrian Mendes, Perimeter's Chief Executive Officer. "If successful, the trial is expected to support our submission in 2025 to the U.S. Food and Drug Administration for authorization to market B-Series OCT with ImgAssist AI in the United States."

Source

[1] Kim Y, Ganduglia-Cazaban C, Tamirisa N, Lucci A, Krause TM. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2024 Feb 6. doi: 10.1245/s10434-024-14902-z. Epub ahead of print. PMID: 38319511.

About Perimeter Medical Imaging AI, Inc.

Based in Toronto, Canada and Dallas, Texas, Perimeter Medical Imaging AI (TSXV: PINK) (OTC: PYNKF) (FSE: 4PC) 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 is currently being 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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Forward-Looking Statements

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, the expected timing of the completion of full enrollment in Perimeter's clinical trial, Perimeter's expectations regarding the outcomes of the clinical trial, and the expected timing of the installation of ImgClear, 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 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, 2023, which is available on Perimeter's SEDAR+ profile at https://www.sedarplus.ca, and could cause actual events or results to differ materially from those projected in any forward-looking statements. 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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