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Perimeter Medical Imaging AI Announces Alignment with FDA on Key Elements of Ongoing Clinical Trial Evaluating AI-enabled B-Series OCT Medical Imaging Technology

Enhanced Artificial Intelligence Software and Interim Analysis Integrated into Current Study

TORONTO and DALLAS, Sept. 7, 2023 /CNW/ - Perimeter Medical Imaging AI, Inc. (TSXV: PINK) (OTC: PYNKF) (FSE: 4PC) ("Perimeter" or the "Company") – a commercial-stage medical technology company – today provided an update on the clinical development of its ongoing clinical trial evaluating the use of Perimeter B-Series OCT combined with its proprietary ImgAssist AI software during breast conservation surgery. Based on feedback from the U.S. Food and Drug Administration ("FDA"), the Company has reached alignment on key elements of the ongoing clinical trial, including the introduction of an interim analysis, which is expected in the second quarter of 2024.

Adrian Mendes, Perimeter's Chief Executive Officer stated, "This positive interaction with the FDA marks an important milestone in our clinical development program. As a first step, we received regulatory approval to implement our substantially enhanced AI algorithm in the ongoing pivotal clinical trial under the existing study protocol, and we have now aligned on other key elements in order to chart a clear path forward for the development of our B-Series OCT with ImgAssist AI."

Mr. Mendes continued, "Importantly, we will have a planned interim analysis in the trial, which will provide us with an early read-out of results based on the use of the newest algorithm. If key endpoints are met at the time of the interim analysis, we may opt to conclude the trial and begin preparing regulatory submissions supporting market clearance. Alternatively, the interim analysis could support continuing the trial to build a stronger submission package from additional subjects. Ultimately, our goal is to expedite the development of our next-gen AI technology and deliver it to our surgeon customers to improve clinical and economic outcomes in breast surgical oncology."

Dr. Alastair Thompson, Principal Investigator and Professor, Section Chief of Breast Surgery, and Olga Keith Wiess Chair of Surgery at Baylor College of Medicine and Co-associate Director for Clinical Research at the Dan L Duncan Comprehensive Cancer Center, stated, "Having participated in earlier stages of its development, and as principal investigator of the study, I am excited that the clinical trial continues to advance and gather additional clinical data using the updated AI software. There is a strong need for new tools to assist surgeons with 'real-time' margin assessment in the operating room. I believe combining AI with high-resolution imaging has the potential to become a new standard of

care during breast conservation surgery."

Summary of Clinical Trial Updates

- **Clearance to introduce enhanced AI algorithm**
  - Perimeter received approval from the FDA to introduce an enhanced AI algorithm in the ongoing clinical trial under the existing study protocol. As a result, all clinical trial sites will use the updated AI as patients continue to enroll in the ongoing study.
- **Enrollment of additional subjects**
  - In order to obtain statistically significant findings based on the use of the new AI algorithm, Perimeter is permitted to enroll up to 531 subjects.
- **Introduction of interim analysis within study protocol**
  - Perimeter intends to conduct a planned interim analysis in the second quarter of 2024. If statistically significant positive interim results are obtained, the Company may opt to conclude the trial and begin preparing regulatory submissions supporting market clearance. If it is determined that more data is needed, the Company may continue with its clinical trial and anticipates study completion by the end of 2024.
- **Additional clinical trial sites permitted**
  - To further support and expedite patient enrollment, Perimeter has received clearance to increase the number of clinical trial sites, most recently adding Mayo Clinic and Baptist MD Anderson in Florida.
- **Summary of anticipated AI improvements**
  - The new enhanced AI takes advantage of additional training data and Perimeter's latest AI advancements that demonstrate improved sensitivity, specificity, precision, and recall. It is expected that this updated version of ImgAssist AI will contribute to more accurate classification, as well as fewer false positives and negatives.

About Perimeter Medical Imaging AI, Inc.
Based in Toronto, Canada and Dallas, Texas, Perimeter Medical Imaging AI (TSX-V: 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.

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, and the expected details regarding Perimeter's ongoing clinical trials, including the anticipated dates of the planned interim analysis and study completion, 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, 2022, 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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