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Perimeter Medical Imaging AI Announces Important Milestone in ATLAS AI Project With FDA Investigational Device Exemption (IDE) Approval to Launch Clinical Trial Using Perimeter B-Series OCT With ImgAssist AI in Breast Conservation Surgery

Pivotal study to determine the impact of Perimeter's novel OCT imaging technology combined with artificial intelligence on positive margin rates for patients with breast cancer

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, today announced approval of its Investigational Device Exemption ("IDE") application by the U.S. Food and Drug Administration ("FDA") to conduct a multi-center, randomized, double-arm study to evaluate the FDA breakthrough-device-designated Perimeter B-Series OCT imaging system that uses ImgAssist AI technology to identify regions of interest as compared with the current standard of care for patients undergoing breast conservation surgery. It is anticipated that over 300 patients across 8 U.S. clinical sites will participate in the pivotal study to be led by Principal Investigator, Dr. Alastair Thompson at Baylor College of Medicine.

Jeremy Sobotta, Perimeter's Chief Executive Officer stated, "This IDE approval marks another important milestone in our ATLAS AI project, building upon the 'Breakthrough Device Designation' that we received in April, as we transition into clinical validation of the AI-enabled, next generation of our commercially available flagship OCT imaging technology. Trial start-up activities are already underway, with world-class sites and a number of the nation's leading breast surgeons identified to participate in Perimeter's pivotal study, which we anticipate initiating in mid-November at our first site at West Cancer Center's Breast Center in Germantown, Tennessee under the direction of Dr. Richard E. Fine. Our hope is that the data generated from this trial supports our belief that Perimeter's innovative OCT imaging technology will become a trusted tool for surgeons, resulting in better patient outcomes and lower healthcare costs."

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 the Dan L Duncan Comprehensive Cancer Center said, "Currently, approximately one in four women who

undergo breast conservation surgery require reoperation if their surgeon fails to get 'clear' margins. The goal of this pivotal study is to compare the use of Perimeter B-Series imaging technology with artificial intelligence against the standard of care and determine if it can improve surgeon's ability to reduce re-operation rates for breast conservation surgery. Importantly, Perimeter's novel imaging technology with AI fits into the routine surgical process with no additional imposition to the patient as it examines a tissue sample that is already being extracted. There is a strong medical need for tools to help surgeons identify if we have adequately removed the cancerous tissue real-time in the operating room and get it right the first time."

Dr. Richard E. Fine, Director of Education & Research, Margaret West Comprehensive Breast Center, West Cancer Center & Research Institute, commented, "I believe combining optical coherence tomography with artificial intelligence could represent the 'next generation' technology in specimen imaging. As breast cancer surgeons, we understand the physical, emotional, and financial stressors for patients that can come with needing a second surgery. The results from this study will not only help determine if this tool can assist physicians with improving patient outcomes but could also provide evidence of reducing the burden of additional costs within the overall healthcare system."

About Perimeter S-Series OCT

Cleared by the U.S. FDA, 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 B-Series OCT with ImgAssist AI

Perimeter is advancing the development of its proprietary, next-gen "ImgAssist" artificial intelligence 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 coupled with ImgAssist AI, and Perimeter is conducting a randomized, multi-site, pivotal study to evaluate it against the current standard of care and assess the impact on re-operation rates for patients undergoing breast conservation surgery.

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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Shushu Feng
Perimeter Medical Imaging AI, Inc.
Main: 214-845-5154
Toll-free: 888-988-7465 (PINK)
media@perimetermed.com

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