

# Perimeter Medical Imaging AI Announces Initiation of Additional Clinical Trial Site at Baylor College of Medicine in Houston, TX

***Pivotal study underway to assess Perimeter's OCT imaging platform combined with AI technology and its impact 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 expansion of its ongoing pivotal study to include an additional clinical trial site at Baylor College of Medicine in Houston, TX, under the direction of Dr. Alastair Thompson, Principal Investigator of the study.

A multi-center, randomized, two-arm clinical trial is underway to measure the effectiveness of the Perimeter B-Series OCT imaging platform combined with ImgAssist artificial intelligence (AI) technology 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 are expected to participate in the pivotal trial, with study completion anticipated by the end of 2022.

Dr. Alastair Thompson, 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, "Failure to get clear margins in breast cancer surgery is a critical problem that can lead to further complications for patients due to re-operations and higher costs to the overall healthcare system. This pioneering technology allows surgeons to examine an excised tissue sample and identify areas of concern to support 'real-time' margin assessment during a surgery."

Dr. Thompson continued, "Having participated in earlier stages of Perimeter's ATLAS AI project – including contributing to the collection of breast tumor images in order to develop and train the artificial intelligence algorithm – I am excited to act as principal investigator of this pivotal study."

Jeremy Sobotta, Perimeter's Chief Executive Officer stated, "We are proud to partner with leading cancer centers like Baylor to enable the late-stage clinical development of our breakthrough-device-designated Perimeter B-Series OCT platform that includes AI-assisted software. We are also grateful for the grant funding that we received from the Cancer Prevention and Research Institute of Texas (CPRIT), which has supported our ATLAS AI project across multiple stages, culminating in this important pivotal study now underway. We believe our technology has the potential to help breast cancer surgeons improve outcomes

for patients and we look forward to analyzing the data from this study, which is expected to be completed by the end of the year.”

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

Perimeter is advancing the clinical 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. Perimeter B-Series + ImgAssist AI is currently approved for “Investigational Use Only” in the U.S., which means that at this time, only select surgeons have access to this technology by participating in the ongoing pivotal clinical trial.

## **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.

*Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*

## **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, 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](http://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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20220111005571/en/>

Shushu Feng  
Perimeter Medical Imaging AI, Inc.  
Direct: 647-339-7465 (PINK)  
Toll-free: 888-988-7465 (PINK)  
[investors@perimetermed.com](mailto:investors@perimetermed.com)

Source: Perimeter Medical Imaging AI, Inc.