Perimeter Medical Imaging AI Announces U.S. FDA 510(k) Clearance for OCT Imaging System

written by Raj Shah | March 1, 2021

March 1, 2021 (Source) – 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 areas of high unmet medical need, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Perimeter's Optical Coherence Tomography (OCT) Imaging System (v2.1), which is designed to examine tissue microstructures during surgical procedures by providing cross-sectional, real-time margin visualization.

Jeremy Sobotta, Perimeter's Chief Executive Officer, stated, "This is an exciting and important milestone for Perimeter that enables us to bring our 'commercial ready' OCT Imaging System to the U.S. market. Throughout clinical development, we listened to our users, and this clearance covers a product that delivers on their feedback, allowing for a streamlined integration into current intraoperative workflows. We are thrilled to bring physicians our platform providing 'real-time' margin visualization to assist their decision making, and our goal is to help them create better long-term outcomes for patients while lowering costs to the healthcare system."

Mr. Sobotta added, "Our Perimeter OCT Imaging System is the foundational building block that allows us to continue

developing ‘next-gen’ improvements, such as the artificial intelligence tools currently in development under our ATLAS AI project.”

Perimeter’s OCT Imaging System is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization with image review manipulation software for identifying and annotating regions of interest. For more information, please visit: www.perimetermed.com

About Perimeter Medical Imaging AI, Inc.

Perimeter Medical Imaging AI (TSX-V:PINK)(OTC:PYNKF)(FSE:4PC) is a Toronto-based company with U.S. headquarters in Dallas, Texas that is developing, with plans to commercialize, advanced imaging tools that allow surgeons, radiologists, and pathologists to visualize microscopic tissue structures during a clinical procedure. Perimeter’s OCT Imaging platform is a point-of-care imaging system that provides clinicians with real-time, ultra-high-resolution, sub-surface image volumes of the margin (1-2 mm below the surface) of an excised tissue specimen. The ability to visualize microscopic tissue structures during a clinical procedure in addition to standard of care tissue assessment for decision making during the procedure has the potential to result in better long-term outcomes for patients and lower costs to the healthcare system. Perimeter’s OCT Imaging platform is cleared by the FDA as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization, with image review manipulation software for identifying and annotating regions of interest. In addition, Perimeter is developing advanced artificial intelligence/machine learning image assessment tools intended to increase the efficiency of review.

Perimeter's ticker symbol "PINK" is a reference to the pink ribbons used during Breast Cancer Awareness Month by the Canadian Cancer Society and the American Cancer Society, driving home the company's dedication to helping surgeons, radiologists and pathologists use Perimeter's imaging technology and AI (Artificial Intelligence) in the fight against breast cancer, which is estimated to account for 30% of all female cancer diagnoses this year.



Perimeter Medical Imaging AI has received 510(k) clearance from the U.S. FDA for Perimeter's Optical Coherence Tomography (OCT) Imaging System (v2.1) (Photo: Business Wire)

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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 the joint information circular dated May 12, 2020, prepared in respect of the securityholder meetings held on June 17, 2020 a copy of 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.