Perimeter Medical Imaging AI Receives U.S. FDA Breakthrough Device Designation for its Optical Coherence Tomography (OCT) Imaging System with ImgAssist AI

written by Raj Shah | April 15, 2021

April 15, 2021 (Source) – ***New designation provides potential pathway to expedite adoption of Perimeter's transformative medical imaging technology combined with artificial intelligence***

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 today that the U.S. Food and Drug Administration (FDA) has granted the company a Breakthrough Device Designation for its Optical Coherence Tomography (OCT) Imaging System coupled with ImgAssist AI. Perimeter is advancing its proprietary, next-gen artificial intelligence technology and machine learning tools through clinical development under its ATLAS AI project, which is made possible, in part, by a $7.4 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT), a leading state body funding cancer research.

The goal of the FDA's Breakthrough Devices Program is to provide patients and health care providers with timely access to medical devices that provide for more effective treatment or diagnosis

of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment, and review. This designation allows for accelerated interactions with the FDA during product development and prioritized review of future regulatory submissions. In addition, a new Medicare policy program (Medicare Coverage of Innovative Technology, or MCIT) provides national Medicare coverage for up to four years for FDA-designated Breakthrough Devices upon market authorization, enabling more rapid utilization of new and innovative technologies for the Medicare population.

Liz Munro, Perimeter's co-founder and President of Canadian Operations commented, "Since company inception, the Perimeter team's vision has been to develop imaging tools that have the potential to improve outcomes for clinicians, payors and most importantly – patients and their families. We are thrilled that FDA has granted Breakthrough Device Designation for our OCT Imaging System with ImgAssist AI, recognizing the potential of our device to offer significant advantages over existing alternatives for intra-operative evaluation of margins during breast cancer lumpectomy. We are grateful to the FDA review team for our productive interactions, as well as their timely review of this submission, and look forward to working with FDA through the final stages of development and clinical validation of this exciting product."

Jeremy Sobotta, Perimeter's Chief Executive Officer stated, "Achieving a Breakthrough Device Designation from the FDA further validates our strong belief that Perimeter's novel OCT Imaging System combined with AI has the potential to be a transformative, disruptive new technology aimed at helping surgeons treat breast cancer. This Breakthrough Designation, combined with the Centers for Medicare & Medicaid Services' (CMS) initiatives around MCIT, have the potential to provide a pathway to expediting adoption of this innovative technology. We

are committed to providing physicians with ultra-high-resolution images of excised breast tissue ‘real-time’ during a surgical procedure combined with added artificial intelligence tools to help them interpret areas suspicious for cancer, with the goal of improving patient outcomes and lowering healthcare costs.”

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 and commercializing advanced imaging tools that allow surgeons, radiologists, and pathologists to visualize microscopic tissue structures during a clinical procedure. Perimeter’s Optical Coherence Tomography (OCT) Imaging System 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 System 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 advancing its proprietary, next-gen artificial intelligence technology and machine learning tools through clinical development under its ATLAS AI project, which is made possible, in part, by a $7.4 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT). 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 in the fight against breast cancer, which is estimated to account for 30% of all female cancer diagnoses this year.

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Forward-Looking Statements

This news release contains statements that may 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 timing of and results from clinical studies, the clinical development of Perimeter's ImgAssist AI technology, the commercialization of Perimeter's OCT Imaging System, the impact of FDA Breakthrough Designation on future regulatory submissions or Medicare approvals, future financial position, business strategy and strategic goals, competitive conditions, research and development activities, projected costs and capital expenditures, financial results, research and clinical testing outcomes, taxes and plans and objectives of, or involving, Perimeter. Without limitation, information regarding potential future development and commercialization activities 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, 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 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.