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First U.S. Patient Undergoes Successful Minimally Invasive Carpal Tunnel Release Using PAVmed's CarpX® Device

NEW YORK, Feb. 16, 2021 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the "Company" or "PAVmed"), a highly differentiated, multi-product, commercial-stage medical technology company, today announced that the first U.S. patient recently underwent successful carpal tunnel release using its CarpX® minimally invasive carpal tunnel device.

CarpX relieves the symptoms of Carpal Tunnel Syndrome (CTS) in a rapid, minimally invasive, office-based procedure that speeds patients' recovery. CTS is a common workplace-related condition that causes chronic pain to patients and, as the top driver of workmen's compensation claims, imposes high costs on society.

The patient presented with symptoms of carpal tunnel syndrome to Dr. Edward J. Armbruster of Mercer-Bucks Orthopaedics, P.C., in greater Philadelphia, who performed minimally invasive carpal tunnel release using the CarpX device. In marked contrast to typical recovery times of up to several months following conventional carpal tunnel release surgery, the patient returned to work as a truck driver within one week of the procedure.

"This is a very exciting development and the most significant advance in minimally invasive carpal tunnel release since endoscopic techniques were introduced some 30 years ago" said Dr. Armbruster. "I found that the CarpX balloon creates significantly more space in the carpal tunnel after the transverse carpal ligament is divided than traditional techniques, which could potentially result in superior outcomes for patients. As a busy hand surgeon, I strongly believe that CarpX will change how future carpal tunnel surgery will be performed, providing patients with a less invasive option with significantly shorter recovery times than existing carpal tunnel release options."

"We continue to find that CarpX performs as designed, combining balloon technology to protect critical structures together with radiofrequency energy to cut the transverse carpal ligament precisely, offering procedure times comparable to traditional techniques after a very short learning curve," said Dr. Brian deGuzman, PAVmed's Chief Medical Officer, who oversees training and proctoring of early CarpX users and was present as an observer during this procedure.

CarpX has the potential to lower healthcare costs and increase the numbers of patients treated for CTS by offering a more attractive option to the large number of patients who chose to "suffer in silence" to avoid a prolonged recovery from traditional carpal tunnel surgery.

"We thank Dr. Armbruster for leading the team of world-class hand surgeons participating in

our initial U.S. CarpX commercial launch,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer. “We continue to take a steady and deliberate approach to this initial launch, focusing on training, proctoring and procedural streamlining, to lay the foundation for expanded utilization later this year. This initial U.S. commercial experience along with our clinical trial results in New Zealand affirm CarpX’s potential to establish a new standard of care in the treatment of carpal tunnel syndrome by dramatically reducing recovery times and improving outcomes compared to traditional open surgery. We believe this represents an estimated billion-dollar U.S. market opportunity.”

About CarpX

CarpX is a patented U.S. Food and Drug Administration (FDA) 510(k) cleared single-use disposable minimally invasive device designed to treat carpal tunnel syndrome while reducing recovery times ([CarpX animation](#)). CarpX is designed to closely mimic the anatomic results of invasive carpal tunnel surgery, but much less invasively, using catheters, balloons, radiofrequency energy and other established tools that have contributed to percutaneous and minimally invasive revolutions in the treatment of other conditions. The balloon catheter device is inserted under the scarred ligament in a minimally invasive fashion, tensioning it while pushing the nerve and tendons away. When activated, bipolar radiofrequency electrodes precisely cut the ligament from the inside out in a matter of seconds. The device design provides physicians with ongoing feedback to optimize the safety and completeness of the procedure. Carpal tunnel syndrome exacts a major clinical and economic burden on society with an estimated 600,000 patients undergoing carpal tunnel surgery each year and over one million who suffer in silence because of the long recovery times associated with traditional invasive carpal tunnel release.

About PAVmed

PAVmed Inc. is a highly differentiated, multi-product, commercial-stage medical device company employing a unique business model designed to advance innovative products to commercialization rapidly and with less capital than the typical medical device company. This proprietary model enables PAVmed to pursue an expanding pipeline strategy with a view to enhancing and accelerating value creation while seeking to further expand its pipeline through relationships with its network of clinician innovators at leading academic centers. PAVmed’s diversified product pipeline addresses unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its four operating divisions include GI Health (EsoGuard[®] Esophageal DNA Test, EsoCheck[®] Esophageal Cell Collection Device, and EsoCure[™] Esophageal Ablation Device with CalduS[™] Technology), Minimally Invasive Interventions (CarpX[®] Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO[™] Implantable Intraosseous Vascular Access Device and NextFlo[™] Highly Accurate Infusion Platform Technology), and Emerging Innovations (non-invasive laser-based glucose monitoring, pediatric ear tubes, and mechanical circulatory support). For more information, please visit www.pavmed.com, follow us on [Twitter](#), connect with us on [LinkedIn](#), and watch our videos on [YouTube](#). For more information on our majority owned subsidiary, Lucid Diagnostics Inc., please visit www.luciddx.com, follow Lucid on [Twitter](#), and connect with Lucid on [LinkedIn](#). For detailed information on EsoGuard, please visit www.EsoGuard.com and follow us on [Twitter](#), [Facebook](#) and [Instagram](#).

Forward-Looking Statements

This press release includes forward-looking statements that involve risks and uncertainties. Forward-looking statements are statements that are not historical facts. Such forward-looking statements, based upon the current beliefs and expectations of PAVmed's management, are subject to risks and uncertainties, which could cause actual results to differ from the forward-looking statements. Risks and uncertainties that may cause such differences include, among other things, volatility in the price of PAVmed's common stock, Series W Warrants and Series Z Warrants; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance PAVmed's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from PAVmed's preclinical studies; whether and when PAVmed's products are cleared by regulatory authorities; market acceptance of PAVmed's products once cleared and commercialized; our ability to raise additional funding and other competitive developments. PAVmed has not yet received clearance from the FDA or other regulatory body to market many of its products. The Company has been monitoring the COVID-19 pandemic and its impact on our business. The Company expects the significance of the COVID-19 pandemic, including the extent of its effect on the Company's financial and operational results, to be dictated by, among other things, the success of efforts to contain it and the impact of actions taken in response. New risks and uncertainties may arise from time to time and are difficult to predict. All of these factors are difficult or impossible to predict accurately and many of them are beyond PAVmed's control. For a further list and description of these and other important risks and uncertainties that may affect PAVmed's future operations, see Part I, Item 1A, "Risk Factors," in PAVmed's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as the same may be updated in Part II, Item 1A, "Risk Factors" in any Quarterly Report on Form 10-Q filed by PAVmed after its most recent Annual Report. PAVmed disclaims any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in its expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

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Attachment

- [CarpX® Minimally Invasive Carpal Tunnel Device](#)



Source: PAVmed Inc.

CarpX® Minimally Invasive Carpal Tunnel Device



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