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PAVmed Receives FDA 510(k) Clearance for its CarpX™ Minimally Invasive Carpal Tunnel Device

NEW YORK, April 21, 2020 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ**) (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced it has received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for its CarpX™ minimally invasive carpal tunnel device.

PAVmed Inc.

The FDA determined that CarpX is "substantially equivalent to legally marketed predicates" and that PAVmed may market CarpX for "the minimally invasive isolation and incision/division of ligaments, tendons, or fascia such as the transverse carpal ligament for treatment of carpal tunnel syndrome." The FDA reached this determination after reviewing detailed data from the Company's successful CarpX clinical safety study performed in New Zealand.

"We are very excited to introduce CarpX as the first 510(k)-cleared minimally invasive device to utilize common catheter, balloon and wire techniques to facilitate carpal tunnel release," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer. "We believe CarpX will revolutionize the treatment of carpal tunnel syndrome, a widely prevalent condition that exacts a significant clinical and economic burden on society, by dramatically reducing recovery times compared to traditional open surgery – an estimated billion-dollar U.S. market opportunity. We look forward to offering CarpX's benefits to patients and their physicians following its upcoming commercial launch. We have identified an outstanding national sales manager candidate with over twenty-two years of experience calling on orthopedic and hand surgeons to lead this effort, working closely with our clinical,

manufacturing and commercial teams."

"This very important milestone could not have been reached without the tenacious hard work, singular expertise, and relentless perseverance of our entire team, including our world-class regulatory consultants at Hogan Lovells, LLP and product development and manufacturing partners at Sage Product Development, Inc.," Dr. Aklog added. "We also owe a debt of gratitude to the team at the FDA for completing their work expeditiously, despite the strain on resources from the current pandemic."

"Observations from our clinical safety study strongly support CarpX's clinical and commercial potential," said Brian J. deGuzman, M.D., PAVmed's Chief Medical Officer, who trained the surgeons and was present in the operating room for all procedures. "CarpX performed flawlessly as a precision cutting device, consistently and cleanly cutting the ligament without evidence of thermal spread beyond the target tissue cut line. Procedure times fell after a short learning curve, indicating the CarpX procedure can be performed in the same or less time as traditional open carpal tunnel release, using 5-10 mm keyhole incisions and with no incision crossing the base of the palm, the problematic area for healing, recovery and persistent pain after traditional surgery. CarpX's balloon also appeared to create more space within the carpal tunnel at completion of the procedure which has the potential to enhance both short and long-term outcomes."

As previously announced, all twenty patients in the Company's successful CarpX clinical safety study in New Zealand underwent successful CarpX minimally invasive carpal tunnel release and met the pre-specified effectiveness endpoint – clinical device technical success defined as the endoscopic confirmation of complete division of the transverse carpal ligament. Two-week and 90-day post-operative follow-up rates were 100% and 95%, respectively. All patients who completed follow-up also met the study's pre-specified primary safety endpoint – device safety defined as no serious device-related adverse events. Results of additional pre-specified outcome assessments were excellent and similar to, or better than, expected results following traditional open carpal tunnel release.

About CarpX

CarpX is a patented single-use disposable minimally invasive device designed to treat carpal tunnel syndrome while reducing recovery times. 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 designed to be inserted under the scarred ligament in a minimally invasive fashion, 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.

About PAVmed

PAVmed Inc. is a highly differentiated, multiproduct commercial stage medical device company employing a unique business model designed to advance innovative products to commercialization much more rapidly and with significantly 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 Intraosseus Vascular Access Device and NextFlo™ Highly Accurate Disposable Intravenous Infusion Set), and Emerging Innovations (non-invasive laser-based glucose monitoring, NextCath™ self-anchoring catheters, 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.

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 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. 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 IA, "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 Reports 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.

Contacts:

Investors
Mike Havrilla

Director of Investor Relations
(814) 241-4138
JMH@PAVmed.com

Media
Shaun O'Neil
Chief Commercial Officer
(518) 812-3087
SMO@PAVmed.com

Attachment

- CarpX™ Minimally Invasive Carpal Tunnel Device

Source: PAVmed Inc.