March 9, 2020

PAVmed Announces FDA 510(k) Re-submission for its CarpX™ Minimally Invasive Carpal Tunnel Device

Incorporates data from successful clinical safety study in which all patients met pre-specified safety and effectiveness endpoints

NEW YORK, March 09, 2020 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ**) (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced the U.S. Food and Drug Administration (FDA) has acknowledged receipt of a 510(k) premarket notification submission for the Company's CarpX™ minimally invasive carpal tunnel device. This re-submission incorporates data from the Company's successful first-in-human CarpX clinical safety study, in which all patients met the study's pre-specified safety and effectiveness endpoints.

"We look forward to completing the U.S. regulatory process for CarpX so we can begin offering this groundbreaking technology for alleviating carpal tunnel syndrome to physicians and their patients," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer. "We believe the data in this 510(k) re-submission demonstrate the safety and effectiveness of CarpX as well as its substantial equivalence to the predicate device. As expected, our clinical safety study found CarpX to be a precision cutting device, consistent with its design and the results of extensive pre-clinical testing, meeting both pre-specified safety and effectiveness endpoints, with no device-related adverse events. Based on these results, we believe CarpX has the potential to transform carpal tunnel syndrome treatment by dramatically reducing recovery times compared to traditional open surgery, an estimated billion-dollar U.S. market opportunity."

PAVmed is seeking FDA 510(k) clearance to market CarpX for minimally invasive carpal tunnel release. Extensive pre-clinical testing, performed under close FDA consultation, demonstrated that CarpX was safe, effective and substantially equivalent to the selected predicate. This testing specifically documented a very precise thermal profile, with negligible thermal energy spread beyond the target tissue cut line, as recommended by the FDA.

The FDA subsequently recommended a clinical safety study to support 510(k) re-submission. The Company consulted closely with the FDA during development of the study protocol, which it then utilized in its recently completed CarpX first-in-human clinical safety study. Twenty carpal tunnel syndrome patients in New Zealand underwent successful CarpX minimally invasive carpal tunnel release. All patients met the study's pre-specified effectiveness endpoint – clinical device technical success defined as *the ability of CarpX to perform complete division of the transverse carpal ligament (TCL) as assessed by post-procedural endoscopic inspection of the TCL after treatment*. Two-week and 90-day post-operative follow-up rates were 100% and 95%, respectively, exceeding the target 80% rate recommended by the FDA. The only loss to follow-up was a patient who was documented to

be “back to normal” with resolution of symptoms at six weeks, but opted not to return to the study site because he was traveling a significant distance away and was overall very satisfied with the procedure’s outcome.

All patients who completed follow-up met the study’s pre-specified primary safety endpoint – device safety defined as *no serious adverse event probably or definitely related to the device resulting in significant morbidity through 90-day follow-up*. Patients underwent additional pre-specified outcome assessments at baseline and during post-operative follow-up, using well-established, standardized and validated measures to assess patient satisfaction, as well as changes in symptoms, motor and sensory function and neurophysiological parameters following carpal tunnel release. These outcome assessments included the Global Satisfaction Questionnaire, QuickDASH and Boston Carpal Tunnel Syndrome (BCTQ) Questionnaires, Ten Test and Semmes-Weinstein Monofilament sensory tests, Grip and Pinch Strength motor function tests, as well as nerve conduction and electromyographic studies. The excellent results of these pre-specified outcome assessments following CarpX minimally invasive carpal tunnel release were similar to, or better than, expected results following traditional open surgery.

Additional observations from the study strongly support CarpX’s clinical and commercial potential. Surgeons were able to achieve the same anatomic result as traditional open surgery using a minimally invasive approach. Endoscopic visualization showed that CarpX cut the ligament cleanly and precisely, without evidence of thermal spread beyond the target tissue cut line. Procedure times fell after a short learning curve, indicating that CarpX minimally invasive carpal tunnel release can be performed in the same or less time as traditional open surgery. The final set of procedures were performed through 5-10 mm keyhole incisions, with no incision crossing the base of the palm, an area known to be problematic for healing, resulting in delayed recovery and persistent pain after traditional open surgery. The surgeons also observed that the CarpX balloon appeared to create more space within the carpal tunnel than traditional carpal tunnel release, which could favorably impact long-term outcomes.

About CarpX

CarpX is a patented single-use disposable minimally invasive device designed to treat carpal tunnel syndrome while reducing recovery times. PAVmed believes CarpX will dramatically reduce recovery times compared to traditional open surgery while targeting an estimated $1 billion immediately addressable domestic market opportunity. 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

Source: PAVmed Inc.