## ADDING MULTIMEDIA PAVmed Successfully Completes CarpX™ Pre-Clinical Study

- Device designed to revolutionize treatment of Carpal Tunnel Syndrome -
- Completely percutaneous procedure would replace invasive surgery -



NEW YORK--(BUSINESS WIRE)-- PAVmed Inc. (Nasdaq:PAVMU), an innovative multi-product medical device company, today announced the successful completion of a pre-clinical human cadaver study, demonstrating that the Company's completely percutaneous CarpX™ device reliably and effectively transects the ligament which causes Carpal Tunnel Syndrome (CTS).

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PAVmed's CarpX device, a completely percutaneous device to treat carpal tunnel syndrome. For more information, visit pavm.com.(Photo: Business Wire)

Lishan Aklog, M.D., Chairman and CEO of PAVmed, said "We are excited to report that CarpX performed very well in this important pre-clinical study. The device consistently cut the ligament from the inside out, replicating the anatomic result of traditional, invasive carpal tunnel surgery, but without the need for a surgical incision."

"In accordance with PAVmed's proven business model, we are now aggressively proceeding towards completion of commercial design, validation/verification testing and FDA submission with clearance and commercialization targeted for 2017. We estimate the market opportunity for CarpX to be over \$1 billion based on the current rate of surgical procedures," Dr. Aklog concluded.

Dr. Brian deGuzman, Chief Medical Officer of PAVmed, stated "Carpal Tunnel Syndrome affects millions of people and is one of the most common and economically burdensome occupational injuries in the nation. Its incidence is expected to further grow as a result of aggressive thumb typing and smartphone use." 1,2

"Most patients choose to avoid or delay treatment until symptoms become debilitating because they are concerned about the pain, scarring and recovery time associated with the traditional invasive surgical approach. As a completely percutaneous device, we believe CarpX will expand the market by lowering the threshold for patients to pursue treatment," Dr. deGuzman added.

The symptoms of CTS result from compression of the median nerve by an inflamed or scarred Transverse Carpal Ligament (TCL) located near the wrist. In traditional, invasive carpal tunnel surgery, the physician cuts the TCL working through an open surgical incision in the hand, with or without the help of an endoscope. Approximately 600,000 patients undergo this procedure each year in the U.S.3

CarpX consists of a balloon catheter with integrated bipolar radiofrequency cutting electrodes, which is introduced into the carpal tunnel percutaneously over a guidewire, without an open surgical incision. Once its position is confirmed by ultrasound, the balloon is inflated, stretching the TCL over the electrodes and pushing

the median nerve and other structures safely away. A brief burst of radiofrequency energy cuts the ligament, relieving the compression of the median nerve.

"As a dramatically less-invasive percutaneous treatment option, CarpX has the potential to reduce pain and recovery time and to be more cost-effective by shortening procedural times and shifting care from the operating room to less costly treatment settings," Dr. deGuzman added. "We expect to be able to provide patients and their physicians with this exciting new solution in 2017."

CarpX was tested in 14 human cadaver arms. In one group, the device was positioned within the carpal tunnel, after exposing the TCL, to directly observe the cutting of the ligament. In a second group, the device was inserted percutaneously under ultrasound guidance. The device reliably and effectively cut the ligament, cleanly and without charring or collateral injury, in under 1.5 seconds. The full data from the study will be submitted for publication in a peer-reviewed journal.

## **About Carpal Tunnel Syndrome (CTS)**

CTS is a cumulative trauma disorder that occurs most commonly in middle-aged individuals especially those who perform repetitive tasks involving the hands, such as assembly line workers, typists, data-entry personnel and laboratory workers. Cumulative trauma from repetitive motion results in compression of the median nerve by the transverse carpal ligament as the nerve passes from the wrist to the hand. This in turn results in progressive numbness, tingling, pain and weakness. According to the 2010 National Health Interview Survey, approximately five million Americans suffer from CTS.4 It accounts for billions of dollars of lost workplace productivity each year and results in approximately three million office visits5 and 600,000 surgical procedures per year.

## About PAVmed

PAVmed Inc. (Nasdaq:PAVMU) is an innovative multi-product medical device company developing and commercializing a diversified pipeline of products which address unmet clinical needs, utilizing a proven *Innovating at the Speed of Life* ™ business model focused on capital efficiency and speed to market. PAVmed's pipeline of products have attractive regulatory pathways and market opportunities and encompass a broad spectrum of clinical areas including carpal tunnel syndrome (CarpX), medical infusions (NextFlo and NextCath), interventional radiology (PortIO™ and NextCath), tissue ablation and cardiovascular intervention (Caldus™). The Company intends to further expand its pipeline through engagements with clinician innovators and leading academic medical centers. For further information please visit www.pavm.com.

## **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 the Company's management, are subject to risks and uncertainties, which could cause actual results to differ from the forward-looking statements. PAVmed has not yet sought or received clearance from the FDA or other regulatory body to market any of its products including CarpX.

- 1 American Academy of Orthopedic Surgeons. Management of Carpal Tunnel Syndrome Evidence-Based Clinical Practice Guideline. <a href="https://www.aaos.org/ctsguideline">www.aaos.org/ctsguideline</a>. Published February 29, 2016.
- 2 US Bureau of Labor and Statistics, US Department of Labor, 2011. Nonfatal occupational injuries and illnesses requiring days away from work, 2010. USDL report number: 11-1612.
- 3 Fajardo M, Kim SH, Szabo RM. Incidence of carpal tunnel release: trends and implications within the United States ambulatory care setting. J Hand Surg Am. 2012 Aug;37(8):1599-605.
- 4 Luckhaupt SE, Dahlhamer JM, Ward BW, Sweeney MH, Sestito JP, Calvert GM. Prevalence and work-relatedness of carpal tunnel syndrome in the working population, United States, 2010 National Health Interview Survey. Am J Ind Med. 2013 Jun;56(6):615-24.
- 5 Annual Number and Percent Distribution of Ambulatory Care Visits by setting type according to Diagnosis Group, United States, 2009-2010. Source: CDC/NCHS, National Ambulatory Medical Care Survey, National Hospital Ambulatory Medical Care Survey.

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