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PAVmed's PortIO™ Intraosseous Infusion System Achieves Multiple Milestones

Unprecedented six-month maintenance-free implant duration achieved

FDA pre-submission meeting date supporting de novo application secured

Broad method and device patents granted by USPTO

NEW YORK, Nov. 07, 2019 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ**) (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced that its groundbreaking PortIO™ Intraosseous Infusion System has achieved multiple important development, regulatory and intellectual property (IP) milestones towards establishing the first commercially available implantable intraosseous vascular access device.

PAVmed completed a pre-clinical animal study documenting a maintenance-free implant duration over six months, an important clinical threshold in long-term infusion applications. The Company also secured a pre-submission meeting with the U.S. Food and Drug Administration (FDA) scheduled for January 8, 2020 during which it will review the clinical protocol for a small upcoming first-in-human (FIH) clinical safety study – the final step in its *de novo* application. Finally, the U.S. Patent and Trademark Office (USPTO) has granted U.S. Patents 10,426,940 and 10,434,296, entitled "Intraosseous Infusion Ports" which include broad independent claims covering the device technology and methods underlying PortIO. The patents, assigned to PAVmed at its founding, lists Lishan Aklog, M.D., PAVmed's Chairman & CEO, and Brian J. deGuzman, M.D., its Chief Medical Officer, as inventors. They further expand PAVmed and its subsidiaries growing IP portfolio that now includes over 100 patents and patent applications across 17 families.

"PortIO is a very important, and I believe underappreciated, value driver in our lead product portfolio," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer. "PortIO promises to provide dialysis patients and those with poor venous access a superior alternative to traditional vascular access devices, representing an immediately addressable market opportunity of over $700 million. These important milestones put us in an excellent position to complete a small clinical safety study, secure regulatory clearance and commercialize a highly differentiated maintenance-free device with strong IP protection addressing a significant unmet clinical need."

All long-term vascular access devices, including peripherally inserted central catheters (PICC), tunneled central venous catheters and implantable venous ports, require regular flushes by a skilled healthcare professional to prevent them from clotting. These maintenance requirements are labor intensive, costly and interfere with a patient's activity. Improper flushing techniques and other factors can result in serious or even deadly complications, including bloodstream infections, air embolism and life-threatening blood clotting reactions to the drug Heparin used in flushes.

“PAVmed has now extended the maintenance-free implant duration in pre-clinical testing beyond the requirements of nearly all long-term infusion applications in clinical practice,” said Timothy P. Murphy, M.D., former President of the Society of Interventional Radiology (SIR). “I continue to believe that if these results are replicated in clinical practice, PortIO could represent one of the most important advances in long-term vascular access that I have seen during my career, providing significant benefit to a multitude of patients and the healthcare system as a whole – particularly patients with poor venous access, those on, or expected to need, hemodialysis and those with known adverse reactions to the blood thinner Heparin.”

The FDA pre-submission filing incorporated data from extensive pre-clinical testing performed in close consultation with the FDA, including a GLP animal study along with supplemental cadaver and animal studies. It includes a detailed protocol for an FIH small clinical safety study to support an initial indication for a seven-day implant duration through the *de novo* pathway. The Company is proposing a single-center prospective study to be performed in New Zealand with up to 25 patients who require infusions of fluids or medications for up to seven days undergoing PortIO implantation. The proposed primary effectiveness endpoint is successful PortIO implantation and infusion. The proposed primary safety endpoint is freedom from serious device-related adverse events through a 30-day post-explant follow-up period. In anticipation of FDA sign-off on the protocol following the January 8th meeting, the Company has already initiated the study logistics in New Zealand with the goal of launching the study immediately following the FDA meeting and completing enrollment soon thereafter. The clinical data will then be submitted to the FDA as part of a final *de novo* application package.

About PortIO

The PortIO Intraosseous Infusion System consists of an implantable intraosseous vascular access device and insertion kit. Instead of a catheter located in a vein, it has a short extension from the device, which a physician inserts into a bone, leaving the device to reside completely beneath the skin. This allows direct access to the bone marrow, which is a well-established route for the delivery of medications, fluids and other substances. PortIO can be inserted and removed near-percutaneously without requiring a surgical pocket or significant dissection and does not require confirmation of the position of the tip by x-ray or other means. Once in place, the device can be accessed by the nurse through the skin using the same techniques as existing implantable ports. PortIO addresses known limitations of existing long-term vascular access devices which, in addition to the need for regular maintenance with flushes, include occlusion from blood clots, bloodstream infections and difficult or impossible insertion in patients with poor veins. PortIO’s addressable market opportunity is estimated to be at least $700 million based on short-term patients with poor veins and medium or long-term patients who would benefit from its advantages over existing devices. This estimate does not include a separate, possibly larger, market opportunity in patients with renal failure whose veins must be carefully preserved for future hemodialysis.

About PAVmed

PAVmed Inc. is a highly differentiated, multiproduct 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. PAVmed's diversified pipeline of products address unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its five lead technologies provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoGuard™/EsoCheck™), vascular access (PortIO™), pediatric ear infections (DisappEAR™) and medical infusions (NextFlo™). The company is also developing innovative products in other areas, such as catheters and tissue ablation, while seeking to further expand its pipeline through engagements with clinician innovators and leading academic medical centers. 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 any 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.

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Attachment

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