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PAVmed Subsidiary Lucid Diagnostics Files 510(k) Submission with FDA for EsoCheck™ Cell Collection Device

NEW YORK, Nov. 29, 2018 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ**) (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of a 510(k) premarket notification submission for the EsoCheck™ Cell Collection Device (CCD) which its subsidiary Lucid Diagnostics filed on November 21, 2018.

"The EsoCheck CCD 510(k) submission is a critical first step in realizing the enormous potential of this groundbreaking alternative to endoscopy," said Lishan Aklog M.D., PAVmed's Chairman and CEO. "I am so proud that our team was able to achieve this milestone ahead of schedule and underbudget, a mere six months after we founded Lucid and licensed EsoCheck from Case Western Reserve University. Given the excellent predicates and low risk profile, I am optimistic that EsoCheck CCD will be cleared expeditiously and available for clinical use in early 2019."

EsoCheck is a revolutionary technology designed to allow patients to undergo a non-invasive five-minute office-based procedure to detect Barrett's Esophagus (BE), a pre-cursor to highly lethal esophageal cancer, which occurs in patients with chronic heart burn or acid reflux (GERD). EsoCheck was highlighted as one of the year's significant advances in cancer prevention in the National Cancer Institute's 2020 Annual Plan and Budget Proposal to Congress. The Company believes EsoCheck has the potential to save many lives through the early detection of BE, which can be carefully monitored and treated with non-surgical approaches if detected before cancer develops. The immediately addressable domestic market opportunity for EsoCheck is estimated to be at least $2 billion based on over 20 million U.S. patients with GERD who are candidates for BE screening based on existing American College of Gastroenterology (ACG) guidelines.

EsoCheck CCD™ is a balloon catheter designed to collect cells for diagnostic testing from a targeted region of the esophagus without the need for endoscopy. The other component of the EsoCheck technology is EsoCheck Dx™, a methylated DNA biomarker test (mVIM + mCCNA1) which has been shown in a published human study to be highly accurate at detecting BE.

EsoCheck is progressing on schedule through a carefully crafted two-phase regulatory and commercialization strategy which seeks to maximize EsoCheck's long-term commercial opportunity while providing near-term value-inflection commercial milestones. Phase I seeks to commercially launch EsoCheck CCD as a 510(k)-cleared cell collection device and EsoCheck Dx as a Laboratory Developed Test (LDT) which does not currently require FDA review. Phase II seeks a specific indication for widespread BE screening using EsoCheck based on ACG guidelines.

Lucid Diagnostics recently held a lunch symposium on EsoCheck at the 2018 American College of Gastroenterology (ACG) meeting in Philadelphia. An overview of the EsoCheck technology is provided in this 15-minute video presentation by EsoCheck co-inventor Amitabh Chak M.D., professor of medicine at Case Western University School of Medicine and gastroenterologist at University Hospitals Digestive Health Institute.

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 four lead products provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoCheck™), vascular access (PortIO™) and pediatric ear infections (DisappEAR™). The company is also developing innovative products in other areas, such as medical infusions 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.

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, factors affecting the timing and effectiveness of the registration statement for our proposed rights offering; 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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