

PAVmed Subsidiary Lucid Diagnostics Announces Commercial Launch of EsoGuard Esophageal DNA Test

First commercially available DNA test designed to facilitate the diagnosis of Barrett's Esophagus and related precursors to highly lethal form of esophageal cancer

First patients to undergo testing today at gastroenterology center of excellence

NEW YORK, Dec. 19, 2019 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced that its majority owned subsidiary, Lucid Diagnostics Inc. ("Lucid") has launched its EsoGuard™ Esophageal DNA Test as a Laboratory Developed Test (LDT), after completing CLIA/CAP certification of the test at Lucid's commercial diagnostic laboratory partner ResearchDx Inc. dba Pacific Dx ("ResearchDx"), headquartered in Irvine, CA. EsoGuard is the first such DNA test designed to facilitate the diagnosis of Barrett's Esophagus (BE) and related precursors to highly lethal esophageal adenocarcinoma (EAC).

"This major commercialization milestone is a testament to the hard work and dedication of the Lucid team, our world-class partners at ResearchDx and our innovative colleagues on the Case Western Reserve faculty," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer and Lucid's Executive Chairman. "We created Lucid Diagnostics and licensed this groundbreaking technology to eradicate the scourge of deaths from esophageal cancer by detecting Barrett's Esophagus in high-risk patients with chronic heartburn (GERD) early enough to permit careful surveillance and curative treatment. The commercial launch of EsoGuard LDT arms U.S. physicians with a highly accurate diagnostic tool to facilitate the noninvasive diagnosis of Barrett's Esophagus and more advanced precursors to esophageal cancer."

EsoGuard LDT is performed on cells which are noninvasively sampled from the distal esophageal lining and shipped in a custom preservative solution to the ResearchDx facility in Irvine, CA where the DNA is immediately extracted. The DNA is then subjected to bisulfite conversion, PCR amplification and next generation sequencing (NGS) to determine the methylation status of 31 sites on the Vimentin (VIM) and CyclinA1 (CCNA) genes. A complex bioinformatics algorithm is used to calculate the percentage of DNA molecules in which a proportion of methylated sites on either gene exceeds a certain threshold, delivering a positive or negative result. A positive result has been associated with the presence of non-dysplastic BE, dysplastic BE or EAC, in a clinical study of 408 patients published in *Science Translational Medicine*, with greater than 90% sensitivity and specificity. A detailed patient report explaining the EsoGuard result is then sent to the referring physician.

The estimated immediately addressable domestic market opportunity for EsoGuard is at least \$2 billion based on very modest penetration of U.S. GERD patients currently recommended for BE screening according to published society guidelines. EsoGuard LDT has secured a CPT reimbursement code from the American Medical Association (AMA) under the Proprietary Laboratory Analysis (PLA) process and successfully advanced the code through the CMS Clinical Laboratory Fee Schedule (CLFS) process securing the gap-fill designation, permitting ongoing coverage discussions with designated Medicare contractors and private payers.

"Over the past year, we have laid the groundwork for today's commercial launch through extensive interactions with the gastroenterology community at major society meetings and individually," said Shaun M. O'Neil, Lucid's Chief Commercial Officer. "We have confirmed that there is a clear and broad consensus in the community that the vast majority of GERD patients are not being screened for Barrett's Esophagus consistent with society guidelines and that a highly accurate test like EsoGuard LDT would be a game changer for their practices. Lucid is commercially launching EsoGuard LDT with a strategy founded on robust education of gastroenterologists, primary care physicians and patients. We have built a commercial infrastructure which we are deploying today to market EsoGuard to the broader physician community."

About EsoGuard

EsoGuard is a revolutionary technology licensed from Case Western Reserve University in 2018 by PAVmed's majority-owned subsidiary, Lucid Diagnostics Inc. ("Lucid"). EsoGuard is designed to facilitate the diagnosis of

Barrett's Esophagus (BE) with and without dysplasia, precursor conditions which can progress to highly lethal esophageal adenocarcinoma (EAC), as well as EAC itself, in patients with chronic heart burn, also known as gastroesophageal reflux disease (GERD). Screening is recommended in millions of high-risk patients to detect and treat BE before it progresses to EAC but performed in only a small subset. In fact, most patients diagnosed with EAC are neither aware of their underlying BE, nor that they missed the opportunity to undergo treatment which could have prevented progression to EAC if the BE had been diagnosed earlier. As a result, over 80% die within five years of diagnosis.

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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