



## **U.S. FDA Grants PAVmed Subsidiary, Lucid Diagnostics, Breakthrough Device Designation for its EsoGuard Esophageal DNA Test**

NEW YORK, Feb. 11, 2020 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the "Company" or "PAVmed"), a highly differentiated, multiproduct medical device company, today announced that the Company's majority owned subsidiary, Lucid Diagnostics Inc. ("Lucid"), has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its EsoGuard™ Esophageal DNA Test on esophageal samples collected using its EsoCheck™ Cell Collection Device in a prevalent well-defined group of patients at elevated risk for esophageal dysplasia due to chronic gastroesophageal reflux disease (GERD).

"EsoGuard's FDA Breakthrough Device designation represents a major milestone for PAVmed and Lucid," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer and Lucid's Executive Chairman. "This designation validates our belief that EsoGuard is a groundbreaking technology that has the potential to have as great an impact on esophageal cancer as widespread Pap screening has had in preventing deaths from cervical cancer. We look forward to working closely with the FDA to advance our EsoGuard in-vitro diagnostic (IVD) clinical development program at an expedited pace."

The FDA Breakthrough Device Program was created to offer patients more timely access to breakthrough technologies which "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" by expediting their development, assessment and review through enhanced communications and more efficient and flexible clinical study design, including more favorable pre/post market data collection balance. Breakthrough Devices receive priority FDA review, and a bipartisan bill before Congress (H.R. 5333) seeks to require Medicare to temporarily cover all Breakthrough Devices for three years while determining permanent coverage.

"I have dedicated my career to the care of patients across the disease spectrum from BE, with and without dysplasia, to lethal esophageal cancer, and have participated in some of the key developments in this field," said Nicholas J. Shaheen MD, MPH, Professor of Medicine and Epidemiology and Chief of the Division of Gastroenterology and Hepatology at UNC HealthCare, Director of the American College of Gastroenterology (ACG) Institute for Clinical Research and Education and lead author of its guidelines on the Diagnosis and Management of Barrett's Esophagus. "I am very excited that the FDA deemed EsoGuard worthy of Breakthrough Device designation. This recognition significantly enhances EsoGuard's potential to prevent deaths from esophageal cancer through early detection of these conditions."

"I am very gratified that FDA agreed with us that EsoGuard satisfies all of its criteria for Breakthrough Device designation for the proposed indications for use," said Alberto Gutierrez, Ph.D., Lucid's regulatory consultant and former director of the FDA's Office of In-Vitro Diagnostics (OIVD). "I have participated in the designation of several IVD Breakthrough Devices and understand the value this brings to Lucid's clinical development program. I look forward to continuing to work with Lucid and FDA as we take advantage of the enhanced and accelerated FDA engagement opportunities granted to Breakthrough Devices."

The EsoGuard Esophageal DNA Test is performed on esophageal samples that are collected using Lucid's FDA 510(k)-cleared EsoCheck™ Esophageal Cell Collection Device. These technologies were highlighted as one of the year's significant advances in cancer prevention in the National Cancer

Institute's [2020 Annual Plan and Budget Proposal](#) submitted to Congress. They are designed to facilitate the diagnosis of Barrett's Esophagus (BE), with and without dysplasia – a progression of precursor conditions that culminate in highly lethal esophageal cancer (EAC) – as well as EAC itself, in patients with chronic heart burn, also known as gastroesophageal reflux disease (GERD).

Although the ACG's professional society practice guidelines recommend screening in millions of high-risk patients to detect and treat BE, with or without dysplasia, before it progresses to EAC, fewer than 10% actually undergo screening using the traditional invasive approach, upper endoscopy. 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 had the BE been diagnosed earlier.

As a result, over 80% die within five years of diagnosis. The estimated immediately addressable domestic market opportunity for EsoGuard is at least \$2 billion based on very modest penetration of the U.S. GERD patients currently recommended for BE screening according to ACG guidelines.

EsoGuard performs next generation sequencing (NGS) of bisulfite-converted DNA to detect methylation at 31 sites on two genes (VIM and CCNA1). EsoGuard has been shown in a 408-patient human study published in *Science Translational Medicine* to be highly accurate at detecting BE, with and without dysplasia, as well as EAC, with greater than 90% sensitivity and specificity.

EsoGuard, which is already commercially available as a Laboratory Developed Test (LDT), is the subject of two Lucid-sponsored international multi-center IVD clinical trials in support of an FDA PMA. The screening study will enroll GERD patients without a prior diagnosis of BE or EAC who satisfy ACG BE screening guidelines. The case control study will enroll patients with a previous diagnosis of non-dysplastic BE, dysplastic BE (both low and high-grade) or EAC. In both studies, EsoGuard will be compared to the gold standard of endoscopy with biopsies. Dr. Shaheen serves as lead investigator for both studies, which will begin enrolling patients in the coming weeks at 60 sites in the U.S. and Europe.

### **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](http://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](http://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](mailto:JMH@PAVmed.com)

Media

Shaun O'Neil

Chief Commercial Officer

(518) 812-3087

[SMO@PAVmed.com](mailto:SMO@PAVmed.com)